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AD HOC OPEN-ENDED WORKING
GROUP ON ACCESS AND
BENEFIT-SHARING
Second meeting
Montreal, 1-5 December 2003

COMPILATION OF SUBMISSIONS ON ACCESS AND BENEFIT-SHARING AS RELATED TO GENETIC RESOURCES RECEIVED BY THE SECRETARIAT PURSUANT TO DECISIONS VI/24 A-D OF THE CONFERENCE OF THE PARTIES

Note by the Executive Secretary

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INTRODUCTION

1. In decisions VI/24 A-D on access and benefit-sharing as related to genetic resources, Parties and relevant organizations were invited to submit information to the Executive Secretary on a number of issues, including the following.

Issues to be addressed by the second meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing

2. In paragraph 8 of the decision VI/24 A, the Conference of the Parties decided to reconvene the Ad Hoc Open-ended Working Group on Access and Benefit-sharing to advise the Conference of the Parties on:

(a) Use of terms, definitions and/or glossary, as appropriate;

(b) Other approaches as set out in decision VI/24 B;

(c) Measures, including consideration of their feasibility, practicality and costs, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted in Contracting Parties with users of genetic resources under their jurisdiction;

(d) Its consideration of any available reports or progress reports arising from the present decision;

(e) Needs for capacity-building identified by countries to implement the Guidelines.

3. In paragraph 9 of the same decision, the Conference of the Parties requested the Executive Secretary to invite Parties, Governments and relevant international organizations to submit information on the issues referred to in paragraphs 8(a), (b), (c) and (e) of the decision and to make this information available to the Working Group and through the clearing-house mechanism.

The role of intellectual property rights in the implementation of access and benefit-sharing arrangements

4. The Executive Secretary was requested, in paragraph 3 of decision VI/24 C, to undertake further information-gathering and analysis with the help of other international and intergovernmental organizations such as the World Intellectual Property Organization and through the Ad Hoc Open-ended Inter-Sessional Working Group on Article 8(j) and Related Provisions, where appropriate, with regard to:

(a) Impact of intellectual property regimes on access to and use of genetic resources and scientific research;

(b) Role of customary laws and practices in relation to the protection of genetic resources and traditional knowledge, innovations and practices, and their relationship with intellectual property rights;

(c) Consistency and applicability of requirements for disclosure of country of origin and prior informed consent in the context of international legal obligations;

(d) Efficacy of country of origin and prior informed consent disclosures in assisting the examination of intellectual property rights applications and the re-examination of intellectual property rights granted;

(e) Efficacy of country of origin and prior informed consent disclosures in monitoring compliance with access provisions;

(f) Feasibility of an internationally recognised certificate of origin system as evidence of prior informed consent and mutually agreed terms; and

(g) Role of oral evidence of prior art in the examination, granting and maintenance of intellectual property rights.

5. In paragraph 4 of the same decision, WIPO was invited to prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by WIPO for requiring the disclosure within patent applications of, *inter alia*:

(a) Genetic resources utilized in the development of the claimed inventions;

(b) The country of origin of genetic resources utilized in the claimed inventions;

(c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;

(d) The source of associated traditional knowledge, innovations and practices; and

(e) Evidence of prior informed consent.

6. In accordance with paragraphs 6, 7 and 8 of decision VI/24 C, Parties were invited to submit case-studies that they consider relevant to the issues specified in paragraphs 3 and 4, to share their national and regional experiences and also to contribute to the further study and analysis of these same issues.

Prior informed consent of indigenous and local communities

7. In paragraph 13 of decision VI/24C, the Executive Secretary was requested to compile information, and to make it available through the clearing house mechanism of the Convention and other means, on the principles, legal mechanisms and procedures for obtaining prior informed consent of indigenous and local communities under national access regimes for genetic resources, and also on assessments of the effectiveness of such mechanisms and procedures, and requested Parties to provide such information to assist the Executive Secretary.

Information related to access and benefit-sharing arrangements

8. In decision VI/24 D, the Conference of the Parties recognized that access to information is an essential instrument in the development of national capacity for dealing with access and benefit-sharing arrangements and important in enhancing the necessary bargaining power of stakeholders in access and benefit-sharing arrangements.

9. The Conference of the Parties also noted that, since the adoption of the Convention, an increasing number of Parties have developed national/regional regimes on access and benefit-sharing and that Parties and stakeholders could learn from sharing their respective experiences relating to the development and implementation of access and benefit-sharing regimes and that the Secretariat of the Convention could assist in disseminating this information among Parties and stakeholders.

10. In paragraph 6 of the same decision, the Conference of the Parties requested Parties and relevant organizations, as appropriate, to make available to the Executive Secretary:

(a) Detailed information on the measures adopted to implement access and benefit-sharing, including the text of any legislation or other measures developed to regulate access and benefit-sharing;

(b) Case studies on the implementation of access and benefit-sharing arrangements;

(c) Other information, such as that listed in decision V/26, paragraph 12.

11. Following the sixth meeting of the Conference of the Parties, notifications were sent out to Parties and relevant organizations respectively on 27 June and 3 July 2003 (reminders were sent out on the 4 October 2002, 21 February 2003), to invite Parties and relevant organizations to submit relevant information to the Executive Secretary, as set out in decisions VI/24 A-D.

12. In addition, in March 2003, the Open-ended Inter-Sessional Meeting on the Multi-Year Programme of Work for the Conference of the Parties up to 2010 invited Parties to provide information to the Executive Secretary on experience gained in the use of the Bonn Guidelines, taking into consideration information to be provided by Parties pursuant to decisions VI/24 A-D. Following the Inter-Sessional Meeting a notification was sent to Parties on 9 April 2003, inviting them to submit this information to the Executive Secretary.

13. Submissions from Parties, non-Parties and relevant organizations received by the Secretariat pursuant to the above requests are compiled in the annex to the present note. They have been reproduced in the form and language in which they were provided.

Parties

1. Colombia
2. Denmark
3. Ethiopia
4. European Commission
5. Mexico
6. Norway
7. Sri Lanka
8. Switzerland
9. United Kingdom

Non-Parties

United States of America

Relevant organizations

World Trade Organization

I. SUBMISSIONS FROM PARTIES

REPUBLICA DE COLOMBIA
Ministerio de Relaciones Exteriores

VAM/CAA 38913 ___

Bogotá D.C., 21 de octubre de 2002

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NOV 07 2002
ACTION VN
FILE
INFO CD, EV, OJ

Señor
Hamdallah Zedan
Secretario Ejecutivo
Convenio de Diversidad Biológica
Montreal

Señor Secretario Ejecutivo:

En atención a su notificación SCBD/SEL/VN/OJ/32173 del 4 de octubre de 2002, el Gobierno de Colombia quisiera destacar como puntos fundamentales a ser discutidos en la próxima reunión del Grupo de Trabajo de Composición Abierta sobre Acceso y Distribución de Beneficios, la revisión de las definiciones y el uso de términos de los lineamientos de Bonn, como quiera que éstos han sido aprobados teniendo en cuenta que la decisión final que se tome al respecto estará basada en las definiciones y términos que logren acordarse.

Igualmente, se estima pertinente, respecto al punto e) a ser discutido en la reunión y que está relacionado con el tema de creación de capacidad, es necesario que se tenga en cuenta que está no es necesaria únicamente con el fin de implementar los lineamientos de Bonn, sino que resulta fundamental para que los países adquieran capacidades necesarias para elaborar sus propios criterios en materia de acceso a recursos genéticos y distribución de beneficios.

Adicionalmente, nos permitimos enviar copia de la Decisión 391 del Acuerdo de Cartagena sobre un régimen común en acceso a recursos genéticos y de la Decisión Andina 486 sobre un régimen común en propiedad intelectual, en versión inglesa (traducción no oficial), con el fin de que, de considerarse pertinente, sean difundidas durante la reunión del Grupo de Trabajo.

Atentamente,

JAIME GIRON DUARTE
Viceministro de Asuntos Multilaterales

Anexos: lo anunciado

Andean Community

DECISION 391

Common Regime on Access to Genetic Resources

THE COMMISSION OF THE CARTAGENA AGREEMENT,

HAVING SEEN:

The Third Temporary Provision of Commission Decision 345 and Board Proposal 284/Rev. 1;

WHEREAS:

The Member Countries have sovereignty over the use and development of their resources, a principle that has also been ratified by the Agreement on Biological Diversity, signed in Rio de Janeiro in June 1992 and legalized by the five Member Countries;
The Member Countries possess a sizeable biological and genetic heritage that should be preserved and developed on a sustainable basis;
The Andean countries are characterized by their multi-ethnic and pluricultural nature;
The biological diversity, the genetic resources, their endemism and rarity, as well as the know-how, innovations and practices of the native, Afro-American and local communities associated with them, have a strategic value in the international context;
It is necessary to recognize the historic contribution made by the native, Afro-American, and local communities to the biological diversity, its conservation and development and the sustained use of its components, as well as to the benefits generated by that contribution;
A close interdependence exists between the native, Afro-American and local communities and the biological resources that should be reinforced, in keeping with the conservation of the biological diversity and the economic and social development of those communities and of the Member Countries;
It is necessary to strengthen integration and scientific, technical and cultural cooperation, while moving ahead with the harmonious and comprehensive development of the Member Countries;
Genetic resources have an enormous economic value as a primary source of products and processes for industry;

DECIDES:

To approve the following:

COMMON REGIME ON ACCESS TO GENETIC RESOURCES

TITLE I
ON THE DEFINITIONS

Article 1.- The following definitions shall apply for purposes of this Decision:

ACCESS: the obtaining and use of genetic resources conserved in situ and ex situ, of their by-products and, if applicable, of their intangible components, for purposes of research, biological prospecting, conservation, industrial application and commercial use, among other things.

ACCESS CONTRACT: agreement between the Competent National Authority in representation of the State, and a person that establishes the terms and conditions for access to genetic resources, their by-products and, if applicable, the associated intangible component.

ACCESS RESOLUTION: an administrative order issued by the Competent National Authority that executes the access to genetic resources or their by-products, after having fulfilled all requirements or conditions stipulated in the access procedure.

BIOLOGICAL DIVERSITY: the variability of living organisms of any source whatsoever, including, among others, land and ocean ecosystems and other aquatic ecosystems, as well as the ecological complexes of which they are a part. Covers the diversity that exists within each species and between species and within ecosystems as a result of natural and cultural processes.

BIOLOGICAL RESOURCES: individuals, organisms or parts of them, populations or any biotic component of value or of real or potential use that contains a genetic resource or its by-products.

BIOTECHNOLOGY: any technological application that utilizes biological systems or live organisms, parts of them or their by-products, to create or modify products or processes for specific uses.

BY-PRODUCT: a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings.

COMPETENT NATIONAL AUTHORITY: State entity or public institution appointed by each Member Country, authorized to supply the genetic resource or its by-products and therefore to sign or supervise the access contracts, to take the actions provided for in this common regime and to ensure their performance.

COUNTRY OF ORIGIN OF THE GENETIC RESOURCE: country that possesses genetic resources in in situ conditions, including those which, having been in in situ conditions, are now in ex situ conditions.

ECOSYSTEM: a dynamic complex of communities of human beings, plants, animals and micro-organisms and their non-living medium that interact as a functional unit.

EX SITU CONDITIONS: those in which the genetic resources are not found in in situ conditions.

EX SITU CONSERVATION CENTER: a person or institution recognized by the Competent National Authority that conserves and collects genetic resources or their by-products outside their in situ conditions.

GENETIC DIVERSITY: variation of genes and genotypes between and within species. Sum total of the genetic information contained in biological organisms.

GENETIC EROSION: the loss of or decrease in genetic diversity.

GENETIC RESOURCES: all biological material that contains genetic information of value or of real or potential use.

IN SITU CONDITIONS: those in which the genetic resources are found in their ecosystems and natural environments; in the case of domesticated or cultivated species or those having escaped domestication, in the environments where they developed their specific properties.

INTANGIBLE COMPONENT: all know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the genetic resource, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes.

NATIONAL SUPPORT INSTITUTION: national institution devoted to biological research of a scientific or technical nature, that accompanies the applicant and participates jointly with it in the access activities.

NATIVE, AFRO-AMERICAN OR LOCAL COMMUNITY: a human group whose social, cultural and economic conditions distinguish it from other sectors of the national community, that is governed totally or partially by its own customs or traditions or by special legislation and that, irrespective of its legal status, conserves its own social, economic, cultural and political institutions or a part of them.

PROGRAM FOR THE LIBERALIZATION OF GOODS AND SERVICES: a program whose purpose is to eliminate levies and restrictions of all kinds on the importation of goods originating in the territory of any Member Country, pursuant to the provisions of the pertinent chapter of the Cartagena Agreement and all other applicable rules and regulations of its body of law.

SUPPLIER OF THE BIOLOGICAL RESOURCE: a person empowered by this Decision and complementary national legislation to supply the biological resource that contains the genetic resource or its by-products.

SUPPLIER OF THE INTANGIBLE COMPONENT: a person that, through an access contract and pursuant to this Decision and to complementary national legislation, is empowered to supply the intangible component associated with the genetic resource or its by-products.

SUSTAINABLE USE: use of the components of biological diversity in a way and at a rate that does not cause their reduction in the long term and that enables them to maintain their possibilities for satisfying the needs and the aspirations of existing and future generations.

SYNTHESIZED PRODUCT: a substance obtained through the artificial processing of genetic information or of information from other biological molecules. Includes semi-processed extracts and substances obtained by converting a by-product through an artificial process (hemisynthesis).

TITLE II
ON THE PURPOSE AND AIMS

Article 2.- The purpose of this Decision is to regulate access to the genetic resources of the Member Countries and their by-products, in order to:

a) Establish the conditions for just and equitable participation in the benefits of the access;
b) Lay the foundations for the recognition and valuation of the genetic resources and their by-products and of their associated intangible components, especially when native, Afro-American or local communities are involved;
c) Promote conservation of the biological diversity and the sustainable use of the biological resources that contain genetic resources;
d) Promote the consolidation and development of scientific, technological and technical capacities at the local, national and subregional levels; and
e) Strengthen the negotiating capacity of the Member Countries.

TITLE III
ON THE SCOPE

Article 3.- This Decision is applicable to genetic resources for which is the Member Countries are the countries of origin, to their by-products, to their intangible components and to the genetic resources of the migratory species that for natural reasons are found in the territories of the Member Countries.

Article 4.- The following are excluded from the scope of this Decision:

a) Human genetic resources and their by-products; and
b) The exchange of genetic resources, their by-products, the biological resources containing them, or their associated intangible components among native, Afro-American and local communities of the Member Countries for their own consumption, based on their customary practices.

TITLE IV
ON THE PRINCIPLES

CHAPTER I
On The Sovereigny over Genetic Resources and Their By-Products

Article 5.- The Member Countries exercise sovereignty over their genetic resources and their by-products and consequently determine the conditions for access to them, pursuant to the provisions of this Decision.

The conservation and sustainable use of the genetic resources and their by-products are regulated by each Member Country in keeping with the principles and provisions of the Biological Diversity Agreement and of this Decision.

Article 6.- The genetic resources and their by-products which originated in the Member Countries are goods belonging to or the heritage of the Nation or of the State in each Member Country, as stipulated in their respective national legislation.

Those resources are inalienable, not subject to prescription and not subject to seizure or similar measures, without detriment to the property regimes applicable to the biological resources that contain those genetic resources, the land on which they are located or the associated intangible component.

CHAPTER II
On The Recognition of Know-how, Innovations and Traditional Practices

Article 7.- The Member Countries, in keeping with this Decision and their complementary national legislation, recognize and value the rights and the authority of the native, Afro-American and local communities to decide

about their know-how, innovations and traditional practices associated with genetic resources and their by-products.

CHAPTER III
On Training, Research, Development and the Transfer of Technology

Article 8.- The Member Countries favor the establishment of scientific and technical training programs, as well as the execution of research projects that promote the identification, registration, characterization, conservation and sustainable use of the biological diversity and of the by-products of genetic resources that help to satisfy local and Subregional needs.

Article 9.- The Member Countries, recognizing that technology, including biotechnology, and both the access to it and its transfer are essential to the attainment of the objectives of this Decision, shall ensure and facilitate, through the corresponding contracts, the access to technologies that utilize genetic resources and their by-products, that are appropriate for the conservation and sustainable use of the biological diversity and that do not cause damage to the environment.

CHAPTER IV
On Subregional Cooperation

Article 10.- The Member Countries shall define mechanisms for cooperation on matters of common interest concerning the conservation and sustainable use of genetic resources and their by-products and the associated intangible components.

They shall also establish Subregional technical and scientific training programs on the information, follow-up, control and evaluation of activities connected with those genetic resources and their by-products and for the performance of joint research.

CHAPTER V
On National Treatment and Reciprocity

Article 11.- The Member Countries grant each other national, and not discriminatory, treatment in matters relating to access to genetic resources.

Article 12.- The Member Countries may grant national and non-discriminatory treatment to third countries that give them equal treatment.

CHAPTER VI
On Precaution

Article 13.- The Member Countries may adopt measures aimed to impeding genetic erosion or the degradation of the environment and of the natural resources. If the danger of serious and irreversible damage exists, the lack of scientific certainty should not be seized upon as a reason for postponing the adoption of effective measures.

The principle of precaution should be applied in keeping with the provisions in the Chapter on the Liberalization Program of the Cartagena Agreement and the other applicable rules and regulations of the body of law of this Agreement.

CHAPTER VII
On Free Subregional Traffic in Biological Resources

Article 14.- Provided that there is no access to the genetic resources contained in the biological resources referred to in this Decision, the provisions of this regime shall not hinder the use of and free movement of in those biological resources, nor the fulfillment of the provisions of the CITES Convention on health, food security, biosecurity and the obligations stemming from the Program of Liberalization of goods and services among Member Countries.

CHAPTER VIII
On The Juridical Security and Transparency

Article 15.- Provisions, procedures and acts of government authorities of the Member Countries with regard to access, shall be clear, effective, well-grounded and lawful.

The actions performed and information provided by individuals shall likewise be lawful, complete and truthful.

TITLE V
ON THE ACCESS PROCEDURE

CHAPTER I
On the General Aspects

Article 16.- All access procedures shall require the presentation, admittance, publication and approval of an application, the signing of a contract, the issuing and publication of the corresponding Resolution and the declarative registration of the acts connected with that access.

Article 17.- The applications for access and access contracts and, if appropriate, accessory contracts shall include conditions like the following:

a) The participation of Subregional nationals in the research on genetic resources and their by-products and on the associated intangible component;
b) Support for research within the jurisdiction of the Member Country of origin of the genetic resource or in any other Subregional Member Country that contributes to the conservation and sustainable use of the biological diversity;
c) The strengthening of mechanisms for the transfer of know-how and technology, including biotechnology, that is culturally, socially and environmentally healthy and safe;
d) The supply of information about the background and status of the science and about other matters that would contribute to a better knowledge of the situation regarding the genetic resource that originated in the Member Country, its by-product or synthesized product and its associated intangible component;
e) The strengthening and development of the institutional capacity of the country or the Subregion in regard to genetic resources and their by-products;
f) The strengthening and development of the capacities of the native, Afro-American and local communities with relation to the associated intangible components, the genetic resources and their by-products;
g) The compulsory deposit of duplicates of all material collected, at institutions designated by the Competent National Authority;
h) The obligation to inform the Competent National Authority about the results of the research carried out; and
i) The terms for the transfer of the material to which third parties are given access.

Article 18.- The documents connected with the access procedure shall appear in a public file that the Competent National Authority shall keep.

That file shall consist of the following, at least: the application; the identification of the applicant, the resource supplier, and the national support person or institution; the site or area to which the access applies; the access methodology; the project proposal; the parts of the access contract that are not subject to confidentiality; the opinion about and registry of visits; and, if applicable, the evaluation studies of the economic, social and environmental impact or of the environmental permits.

Also included in the file are the Resolution executing the access, the reports supplied by the national support person or institution, and the follow-up and supervisory reports provided by the Competent National Authority or the entity delegated to perform that task. That file is open to consultation by any person.

Article 19.- The Competent National Authority may give confidential treatment to data and information supplied to it in the course of the access procedure or the contract performance, and not previously disclosed, which could be put to unfair commercial use by third parties, unless the knowledge of this data and information by the public is necessary to protect the social interest or the environment.

Accordingly, the applicant should state the grounds for its petition, accompanied by a non-confidential summary that will become a part of the public file.

The information or documents referred to in the second paragraph of Article 18 of this Decision cannot be made confidential.

The confidential aspects shall be covered in a separate file, in the custody of the Competent National Authority, and may not be disclosed to third parties, unless that is judicially ordered.

Article 20.- If the petition for confidential treatment fails to comply with the requirements established in the previous article, the Competent National Authority shall deny it as a matter of right.

Article 21.- The Competent National Authority shall keep a public registry where the following information shall be entered, among other data: the Resolution that may possibly deny the petition, the access contract signing, amendment, suspension and termination dates, the date and number of the Resolution executing or canceling it, the date and number of the Resolution, award or sentence determining the nullity or imposing penalties, with an indication of their kind and the parties, and accessory contract signing, amendment, suspension, termination and nullification dates.

That registry shall be of a declaratory nature.

Article 22.- As stipulated in Article 15, the execution of the access is dependent upon the provision of full and reliable information by the applicant, as called for by law.

In this connection, the applicant should present the Competent National Authority with all of the information about the genetic resource and its by-products that it knows or is in a position to know at the moment the application is presented. That information shall include the present and potential uses of the resource, by-product or intangible component, their sustainability and the risks that could result from the access.

The statements made by the applicant in the application and in the contract, including their respective annexes, shall be in the nature of a sworn statement.

Article 23.- The permits, authorizations and other documents that support the investigation, obtaining, provision, transfer, etc., of biological resources, shall not determine, qualify or presume the authorization of the access.

Article 24.- It is forbidden to use genetic resources and their by-products in biological weapons or for practices that are harmful to the environment or to human health.

Article 25.- The transfer of technology shall be carried out in accordance with the provisions contained in the body of law of the Cartagena Agreement, complementary national provisions and such rules and regulations on biosecurity and the environment as the Member Countries may approve.

Article 26.- The access to and transfer of technology subject to patents or other intellectual property rights, shall be accomplished in keeping with the Subregional and complementary national provisions regulating that area.

CHAPTER II
On the Application for Access

Article 26.- The procedure starts with the presentation to the Competent National Authority of an application for access which should contain:

a) Identification of the applicant and, if pertinent, documents that accredit its legal capacity to make a contract;
b) Identification of the supplier of the genetic and biological resources and their by-products or of the associated intangible component;
c) Identification of the national support person or institution;
d) Identification and curriculum vitae of the person responsible for the project and of his working group;
e) The access activity applied for; and
f) The location or area where the access is to be carried out, with an indication of its geographical coordinates.

The application shall be accompanied by the project proposal, considering the referential model the Board approves through a Resolution.

Article 27.- If the application with its accompanying project proposal is complete, the Competent National Authority shall accept it, assign it a presentation or filing date, record it in the report and enter it with a declarative intent in the public registry it shall keep for that purpose and open the corresponding file.

Were the application to be incomplete, the Competent National Authority would return it without delay, indicating the information that is missing, so that it might be completed.

Article 28.- Within five working days following the date of entry of the application in the public registry referred to in the previous article, an extract of that application shall be published in a newspaper with broad national circulation and in another medium of the place where the access is to be effected, so that those that wish to might supply information to the Competent National Authority.

Article 29.- Within thirty working days after its registration, the Competent National Authority shall evaluate the application, make the visits it deems necessary and issue a technical and legal opinion about its propriety or invalidity. That period may be extended to up to sixty working days if the Competent National Authority considers it desirable.

Article 30.- When the time limit stipulated in the previous article expires, or before that, if appropriate, the Competent National Authority shall accept or deny the application, based on the results of the opinion, the records of visits, the information supplied by third parties, and the fulfillment of the conditions established in this Decision.

The applicant shall be advised about the acceptance of the application and project proposal within five working days after this occurs. The access contract shall then be immediately drawn up and negotiated.

In the event that the application and project proposal are denied, this shall be communicated through a justified Resolution and the matter shall be considered finished. This does not, however, preclude the filing of such objections as are in order, according to the procedures established in the national legislation of Member Countries.

Article 31.- If required by the national law of the Member Country or if the Competent National Authority deems it necessary, the applicant shall comply with environmental provisions in effect.

The procedures that should be followed in that event shall be independent from those stipulated in this Decision and may be started beforehand. Nonetheless, they must be concluded before the expiration of the time limit stipulated in Article 29 and must be considered by the Competent National Authority in making its evaluation.

Were the Competent National Authority to require such studies, it could grant the applicant a supplementary period set exclusively in accordance with the time needed to complete and submit them for its consideration.

CHAPTER III
On the Access Contract

Article 32.- The parties to the access contract are:

a) The State, represented by the Competent National Authority; and
b) The applicant requesting the access.
The applicant must be legally empowered to make a contract in the Member Country in which it requests the access.

Article 33.- The terms of the access contract must be in keeping with the provisions of this Decision and Member Country national legislation.

Article 34.- The access contract shall bear in mind the rights and interests of the suppliers of genetic resources and their by-products, the biological resources that contain them and the intangible component as applicable, in accordance with the corresponding contracts.

Article 35.- When access is requested to genetic resources or their by-products with an intangible component, the access contract shall incorporate, as an integral part of that contract, an annex stipulating the fair and equitable distribution of the profits from use of that component.

The annex shall be signed by the supplier of the intangible component and the applicant for the access. It may also be signed by the Competent National Authority, in accordance with the provisions of national law of the Member Country. If that annex is not signed by the Competent National Authority, it shall be subject to the suspensive condition referred to in Article 42 of this Decision.

Failure to comply with the stipulations of the annex shall constitute grounds for the rescission and nullification of the access contract.

Article 36.- The Competent National Authority may enter into access contracts with universities, research centers or well-known researchers to support the execution of several projects, as provided for in this Decision and in keeping with the national legislation of each Member Country.

Article 37.- The ex-situ conservation centers or other institutions that perform activities involving access to genetic resources or their by-products and, if appropriate, the associated intangible component, should enter into access contracts with the Competent National Authority, pursuant to this Decision.

That Authority may likewise sign access contracts with third parties in regard to genetic resources of which the Member Country is the country of origin and which have been deposited at those centers, bearing in mind the rights and interests referred to in Article 34.

CHAPTER IV
On the Execution of the Access

Article 38.- Once the contract has been adopted and signed, the corresponding Resolution shall be issued in a joint act. This resolution shall then be published together with an extract of the contract, in the Official Newspaper or a newspaper with wide national circulation. As of that moment, the access shall be considered to have been granted.

Article 39.- Such contracts as are signed in violation of the provisions of this regime shall be null and void. The nullification procedure shall be subject to the national provisions of the Member Country in which it is invoked.

Article 40.- The rescission or resolution of the contract shall be motive for the official cancellation of the registration by the Competent National Authority.

TITLE VI
ON THE ANCILLARY CONTRACTS TO THE ACCESS CONTRACT

Article 41.- Ancillary contracts are those that are signed in order to carry out activities connected with the genetic resource or its by-products, between the applicant and:

a) The owner, possessor or manager of the land where the biological resource containing the genetic resource is located;
b) The ex situ conservation center;
c) The owner, possessor or manager of the biological resource containing the genetic resource; or
d) The national support institution, with regard to activities that it should perform and that are not a part of the access contract.

Making an ancillary contract does not authorize access to the genetic resource or its by-product, and its contents are subject to the stipulations of the access contract as provided for in this Decision.

The national support institution must be accepted by the Competent National Authority.

Article 42.- Such ancillary contracts as are signed shall include a condition that subjects their execution to that of the access contract.

As of that moment, they shall become effective and binding and shall be governed by the mutually agreed terms, the provisions of this Decision and applicable Subregional and national legislation. The responsibility for their execution and compliance lies only with the parties to the contract.

Article 43.- Without detriment to what has been agreed upon in the accessory contract and independently of it, the national support institution shall be obliged to collaborate with the Competent National Authority in the follow-up and supervision of the genetic resources, by-products or synthesized products and associated intangible components, and to submit reports about the activities for which it is responsible, in the way or with the frequency that the Authority stipulates, according to the access activity.

Article 44.- The nullity of the access contract produces the nullity of the ancillary contract.

The Competent National Authority may also terminate the access contract when the nullity of the ancillary contract is declared, if the latter is essential for the access.

Its amendment, suspension, rescission or resolution may likewise produce the amendment, suspension, rescission or resolution of the access contract by the Competent National Authority if it substantially affects the conditions of the latter contract.

TITLE VII
ON THE LIMITATIONS TO ACCESS

Article 45.- Member Countries may establish, through an express legal rule, partial or total limitations on access to genetic resources or their by-products in the following cases:

a) Endemism, rarity or danger of extinction of species, subspecies, varieties or races or breeds;
b) Vulnerability or fragility of the structure or functioning of the ecosystems that could worsen as a result of access activities;
c) Adverse effects of access activities on human health or on elements essential to the cultural identity of nations;
d) Undesirable or not easily controlled environmental effects of access activities on the ecosystems;
e) Danger of genetic erosion caused by access activities;
f) Regulations on biosecurity; or
g) Genetic resources or geographic areas rated as strategic.

TITLE VIII
ON VIOLATIONS AND SANCTIONS

Article 46.- Any person performing access activities without the respective authorization shall be liable for punishment.

Also to be sanctioned is any person carrying out transactions with regard to by-products or synthesized products of such genetic resources or the associated intangible component, that is not protected by the corresponding contracts, signed in keeping with the provisions of this Decision.

Article 47.- The Competent National Authority, pursuant to the procedure provided for in its own national legislation, may apply administrative sanctions, such as fines, preventive or definitive confiscation, temporary or definitive closing-down of establishments and disqualification of the violator from applying for new accesses in cases of violation of this regime.

Those sanctions shall be applied without detriment to the suspension, cancellation of nullification of the access, the payment of compensation for such damages and losses as are incurred, including those caused to the biological diversity, and the civil and criminal sanctions that may possibly be in order.

TITLE IX
ON THE NOTIFICATIONS BETWEEN MEMBER COUNTRIES

Article 48.- The Member Countries shall notify each other immediately through the Board, of all applications for access and access resolutions and authorizations, as well as of the suspension and termination of such contracts as are signed.

They shall also advise each other about the signing of any bilateral or multilateral agreement on the subject, which must be in keeping with the provisions of this Decision.

Article 49.- Without prejudice to the stipulations of the previous article, the Member Countries shall immediately inform each other through the Board of all provisions, decisions, regulations, judgments, resolutions and other rules and acts adopted nationally that have to do with the provisions of this Decision.

TITLE X
ON THE COMPETENT NATIONAL AUTHORITY

Article 50.- The Competent National Authority shall perform all of the functions conferred on it in this Decision and in Member Country national legislation. In this connection, it shall be empowered to:

a) Issue the necessary internal administrative provisions to comply with this Decision and, until the appropriate Community rules and regulations are enacted, stipulate how the genetic resources and their by-products shall be identified and packed;
b) Receive, evaluate, accept or deny applications for access;
c) Negotiate, sign and authorize access contracts and issue the corresponding access resolutions;
d) Ensure the rights of suppliers of biological resources that contain genetic resources and of the intangible component;
e) Keep the technical files and the Public Registry of Access to Genetic Resources and their by-products;
f) Keep a directory of persons or institutions pre-qualified to perform scientific or cultural support tasks;
g) Amend, suspend, nullify or terminate access contracts and arrange their cancellation, as the case may be, in keeping with the terms of those contracts, this Decision and Member Country legislation;
h) Oppose the suitability of the national support institution proposed by the applicant and demand its replacement by another, suitable one;
i) Supervise and control compliance with the contractual conditions and the provisions of this Decision and accordingly establish such monitoring and evaluation mechanisms as it deems advisable;
j) Review, in keeping with this Decision, contracts involving access already signed with other institutions or persons and carry out the corresponding actions for repossession;
k) Delegate supervisory activities to other institutions, while keeping the responsibility and direction over that supervision, in conformity with national legislation;
l) Supervise the state of conservation of the biological resources containing the genetic resources;
m) Coordinate continuously with its respective liaison institutions all matters having to do with fulfillment of the provisions of this Decision;
n) Keep the national inventory of genetic resources and their by-products;
o) Keep in continuous contact with the competent national offices for industrial property and set up appropriate information systems with them; and
p) All such other functions as the domestic legislation of the Member Country itself may assign it.

TITLE XI
ON THE ANDEAN COMMITTEE ON GENETIC RESOURCES

Article 51.- The Andean Committee on Genetic Resources is hereby created, such to be comprised of the Directors of the Competent National Authorities on matters of Access to Genetic Resources or their representatives, their advisors and such representatives of other interested sectors as each Member Country may designate.

The Committee shall be responsible for:

a) Issuing national and Subregional recommendations for the best possible fulfillment of this Decision;
b) Issuing technical recommendations on such matters as the Member Countries may submit for its consideration;
c) Recommending the mechanisms for establishing an Andean information network on applications for access and access contracts in the Subregion;
d) Recommending and promoting joint actions to strengthen Member Country capacity in research, management and transfer of technology connected with genetic resources and their by-products;
e) Recommending to the Board for adoption through Resolutions, common documentation models, particularly those that will make it possible to easily verify the coding and identification of genetic resources and their by-products, as well as the legality of the access;
f) Promoting management, surveillance, control and supervision of access authorizations relating to genetic resources and their by-products that exist in two or more Member Countries;
g) Recommending and promoting joint emergency plans and warning mechanisms to prevent or resolve problems relating to access to genetic resources or their by-products;
h) Taking cooperative actions with regard to genetic resources or their by-products;
i) Drawing up their own internal regulations;
j) Writing an explanatory manual of this Decision; and
k) Such other functions as the Member Countries may assign to them.

COMPLEMENTARY PROVISIONS

FIRST.- The Member Countries shall, in keeping with their national legislation, set up or reinforce funds or other types of financial mechanisms financed by the profits from the access and resources from other sources to promote compliance with the aims of this Decision, under the direction of the Competent National Authority.

Through the Andean Committee on Genetic Resources, the Member Countries shall design and implement joint programs for the conservation of genetic resources and shall study the viability and desirability of creating an Andean Fund for their conservation.

SECOND.- The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this Decision.

Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents.

THIRD.- The Competent National Offices on Intellectual Property shall require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products or processes whose protection is being requested have been obtained or developed on the basis of genetic resources or their by-products which originated in one of the Member Countries.

The Competent National Authority and the Competent National Offices on Intellectual Property shall set up systems for exchanging information about the authorized access contracts and intellectual property rights granted.

FOURTH.- Such health certificates supporting the export of biological resources as are issued in accordance with Commission Decision 328, its amendments or addenda, shall incorporate the following statement at the end of the format: "Use of this product as a genetic resource is not authorized."

FIFTH.- The Competent National Authority may enter into, with the institutions referred to in Article 36, contracts for the deposit of genetic resources or their by-products or of the biological resources containing them, exclusively for purposes of their care, keeping those resources under its jurisdiction and control.

Likewise, it may make contracts that do not involve access, such as intermediation or administration contracts, in relation to genetic resources or their by-products or synthesized products, in keeping with the provisions of this Regime.

SIXTH.- When requesting access to genetic resources from protected areas or their by-products, the applicant must fulfill, in addition to the stipulations of this Decision, also the special national legislation on the subject.

FINAL PROVISIONS

FIRST.- Any disputes that may arise among Member Countries shall be settled as stipulated in the Andean body of law.

Any disputes that arise with third countries must be settled according to the provisions of this Decision. If a dispute arises with a third country party to the Agreement on Biological Diversity, signed in Rio de Janeiro on June 5, 1992, the solution adopted must also abide by the principles established in that Agreement.

SECOND.- In negotiating the terms of access contracts to genetic resources that originated in more than one Member Country or to their by-products and in carrying out activities connected with that access, the Competent National Authority shall bear in mind the interests of the other Member Countries, which may present their viewpoints and such information as they deem advisable.

THIRD.- The Board, through a Resolution and after hearing the opinion of the Andean Committee on Genetic Resources, may execute or adjust the procedure stipulated in Title V, Chapters I and II of this Decision.

FOURTH.- This Decision shall become effective on the date of its publication in the Official Newspaper of the Cartagena Agreement.

TEMPORARY PROVISIONS

FIRST.- On the date this Decision enters into force, those which possess, for purposes of access, genetic resources originated in the Member Countries, their by-products or associated intangible components, shall negotiate that access with the Competent National Authority pursuant to the provisions of this Decision. Accordingly, the Competent National Authorities shall set the time limits, which cannot exceed twenty-four months as of the date this Decision becomes effective.

Until this requirement is fulfilled, the Member Countries may disqualify such persons, as well as the institutions they represent or on whose account they act, from applying for new accesses to genetic resources or their by-products in the Subregion. This does not preclude the application of such sanctions as are in order once the time limit referred to in the previous paragraph expires.

SECOND.- Contracts or agreements signed by Member Countries or their public or State institutions with third parties in regard to genetic resources, their by-products, the biological resources containing them or associated intangible components, that are not in conformity with this Decision, may be renegotiated or may fail to be renewed, as applicable.

The renegotiation of such contracts or agreements, as well as the signing of new ones, shall be accomplished by common agreement among the Member Countries. To this end, the Andean Committee on Genetic Resources shall establish the common criteria.

THIRD.- The Member Countries may take such legal action as they deem advisable for the repossession of genetic resources of which they are the countries of origin, their by-products and the associated intangible components and for the collection of any damages and compensation to which they are entitled.

Only the State has the legal entitlement to the action for repossession of those genetic resources and their by-products.

FOURTH.- The Board, through a Resolution and after hearing the opinion of the Andean Committee on Genetic Resources, shall establish the necessary systems for the identification and packing of the genetic resources and, if applicable, their by-products.

FIFTH.- Within a period of no more than 30 working days after this Decision enters into force, the Member Countries shall designate the Competent National Authority on access to genetic resources and shall accredit it before the Board.

SIXTH.- The Member Countries, within a period of no more than 30 working days after this Decision enters into force, shall accredit before the Board their representatives to the Andean Committee on Genetic Resources.

SEVENTH.- The Member Countries shall adopt a common regime on biosecurity within the framework of the Agreement on Diversity. To that end, the Member Countries, in coordination with the Board, shall start the respective studies, particularly with regard to the cross-border movement of modified live organisms produced by biotechnology.

EIGHTH.- The Board shall draw up, within a period of three months after the Member Countries present their national studies, a proposal to establish a special regime or a harmonization regulation, as applicable, aimed at reinforcing the protection of know-how, innovations and traditional practices of native, Afro-American and local communities, in keeping with the provision of Article 7 of this Decision, ILO Convention 169 and the Agreement on Biological Diversity.

To that end, the Member Countries should present their respective national studies during the year after this Decision enters into effect.

NINTH.- The Member Countries shall design a training program to strength the capacity of the native, Afro-American and local communities to negotiate the intangible component within the context of access to genetic resources.

TENTH.- The Board, through a Resolution, shall adopt the reference models for the application for access to genetic resources and the access contract, within a period of no more than fifteen days after this Decision comes into effect.

Signed in the city of Caracas, Venezuela on the second of July of nineteen ninety-six.

Andean Community

DECISION 486

Common Intellectual Property Regime
(Non official translation)

THE COMMISSION OF THE ANDEAN COMMUNITY,

HAVING SEEN:

Article 27 of the Cartagena Agreement and Commission Decision 344;

DECIDES:
To replace Decision 344 by the following Decision:

COMMON INTELLECTUAL PROPERTY REGIME

TITLE I
GENERAL PROVISIONS

On National Treatment

Article 1. - Each Member Country shall accord the nationals of other members of the Andean Community, the World Trade Organization, and the Paris Convention for the Protection of Industrial Property, treatment no less favorable than it accords to its own nationals with regard to the protection of intellectual property, subject to the exceptions already provided in articles 3 and 5 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and in article 2 of the Paris Convention for the Protection of Industrial Property.

Member Countries may also accord such treatment to the nationals of a third country under the terms of their respective domestic legislation.

On Most-Favored-Nation Treatment

Article 2.- With regard to the protection of intellectual property, any advantage, favor, privilege, or immunity granted by a Member Country to the nationals of any other Andean Community Member Country shall be accorded to the nationals of all other Members of the World Trade Organization or of the Paris Convention for the Protection of Industrial Property.

The stipulation set forth in the preceding paragraph shall be applicable without prejudice to the reservations provided for in articles 4 and 5 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

On the Biological and Genetic Heritage and Traditional Knowledge

Article 3.- The Member Countries shall ensure that the protection granted to intellectual property elements shall be accorded while safeguarding and respecting their biological and genetic heritage, together with the traditional knowledge of their indigenous, African American, or local communities. As a result, the granting of patents on inventions that have been developed on the basis of material obtained from that heritage or that knowledge shall be subordinated to the acquisition of that material in accordance with international, Andean Community, and national law.

The Member Countries recognize the right and the authority of indigenous, African American, and local communities in respect of their collective knowledge.

The provisions of this Decision shall be applied and interpreted in such a way that they do not contravene the stipulations of Decision 391 and its effective amendments.

On the Periods and Deadlines

Article 4.- The effective periods for carrying out the procedures stipulated in this Decision that are subject to publication or notification shall be counted as of the day following the notification or publication of the act involved, unless stipulated otherwise in this Decision.

Article 5.- When periods are given in days, these shall be considered working days, unless this Decision stipulates otherwise. If the period is stated in months or years, it shall be computed from date to date. If there is no day equivalent to the starting day of the period in the month of expiration, the last day of the month shall be considered the deadline. If the last day is not a working day, then the deadline shall be considered as having been extended to the following working day.

On the Notifications

Article 6.- The competent national office may set up a system of notification to adequately communicate its decisions to the interested parties.

On the Language

Article 7.- Application petitions addressed to the competent national office shall be submitted in Spanish.

Article 8.- All documents that are processed by the competent national offices shall be submitted in Spanish. Otherwise, they shall be accompanied by unauthenticated Spanish translations. The competent national office may, however, dispense with the presentation of the translations of those documents should it deem this advisable.

On the Claim of Priority

Article 9.- The first application for an invention or utility model patent or for the registration of register an industrial design or a trademark that is validly filed in another Member Country or with a national, regional, or international authority to which the Member Country is linked by a treaty establishing an analogous right of priority to that established in this Decision, shall confer on the applicant or the applicant's assignee the right of priority in filing for a patent or registration on the same subject-matter in the Member Country. The scope and effects of the right of priority shall be those provided in the Paris Convention for the Protection of Industrial Property.

The right of priority may be based on a previous application filed with the competent national office in the same Member Country, provided that a previous right of priority was not claimed in that application. In that case, filing a subsequent application claiming priority shall mean abandoning the previous application in respect of the subject matter that is common between the two.

Any application validly accepted for processing as provided for in Articles 33, 119, and 140 of this Decision or in such treaties as are applicable, is acknowledged to confer the right of priority.

In order to qualify for that right, an application claiming priority shall be filed within the following unextendible periods to be counted as from the filing date of the application whose priority is claimed:

a) twelve months for patents on inventions and utility models; and,
b) six months for registrations of industrial designs and trademarks.

Article 10.- For the purposes of the previous article, a declaration shall be submitted accompanied by the pertinent documentation claiming the priority of the previous application and stating its filing date, the office to which it was submitted, when it was granted, and the number assigned to it, if known. The competent national office may prescribe the payment of a fee for processing priority claims.

The declaration and the pertinent documentation shall be submitted together with or separately from the application within the following unextendible periods to be counted as from the filing date of the priority claim:

a) in the case of patents on inventions or utility models: sixteen months; and,
b) in the case of applications for registration of industrial designs or trademarks: nine months.

Also to be presented are a copy of the application whose priority is claimed, certified by the issuing authority, a certificate attesting to the application filing date issued by the same authority, and, if applicable, the proof of payment of the prescribed fee.

No formalities in addition to those stipulated in this article shall be required for purposes of the right of priority.

Article 11. - Failure to comply with the deadlines, present the documents, or pay the fee shall result in the loss of the priority claimed.

On Discontinuance and Abandonment

Article 12.- The applicant may discontinue the application at any time during the process. Discontinuance of a patent or registration application shall bring the administrative proceeding to an end as of the declaration of conclusion by the competent national office and the assigned presentation date shall be lost.

If the discontinuance predates the publication of the application, that application shall not be published. In the case of patents on inventions or utility models or the registration of an industrial design, the information shall be kept confidential and may not be consulted without written consent from the applicant unless the time-limit set forth in article 40 has been reached.

Article 13.- The stipulations of the previous article shall be applicable to the abandonment of the application proceeding as pertinent.

TITLE II
ON PATENTS

CHAPTER I
On Patentability Requirements

Article 14.- The Member Countries shall grant patents for inventions, whether goods or processes, in all areas of technology, that are new, involve an inventive step, and are industrially applicable.

Article 15.- The following shall not be considered inventions:

a) discoveries, scientific theories, and mathematical methods;
b) Any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing;
c) literary and artistic works or any other aesthetic creation protected by copyright;
d) plans, rules, and methods for the pursuit of intellectual activities, playing of games, or economic and business activities;
e) computer programs and software, as such; and,
f) methods for presenting information.

Article 16.- An invention may be deemed new when not included in the state of the art.

The state of the art comprises everything that has been made available to the public by written or oral description, use, marketing, or any other means prior to the filing date of the patent or, where appropriate, of the priority claimed.

Solely for the purpose of determining novelty, the contents of a patent application pending before the competent national office and having a filing date or priority application date earlier than the date of the patent or patent priority application under examination, shall likewise be considered part of the state of the art, provided that the said contents are included in the earlier application when published or that the period stipulated in Article 40 has concluded.

Article 17.- For the purposes of determining patentability, no account shall be taken of any disclosure of the contents of the patent during the year prior to the filing date of the application in the Member Country or during the year before the date of priority, if claimed, providing that the disclosure was attributable to:

a) the inventor or the inventor's assignee;
b) a competent national office that publishes the contents of a patent application filed by the inventor or the inventor's assignee in contravention of the applicable provision; or,
c) a third party who obtained the information directly or indirectly from the inventor or the inventor's assignee.

Article 18.- An invention shall be regarded as involving an inventive step if, for a person in the trade with average skills in the technical field concerned, the said invention is neither obvious nor obviously derived from the state of the art.

Article 19.- An invention shall be regarded as industrially applicable when its subject matter may be produced or used in any type of industry; industry being understood as that involving any productive activity, including services.

Article 20.- The following shall not be patentable:

a) inventions, the prevention of the commercial exploitation within the territory of the respective Member Country of the commercial exploitation is necessary to protect public order or morality, provided that such exclusion is not merely because the exploitation is prohibited or regulated by a legal or administrative provision;
b) inventions, when the prevention of the commercial exploitation within the respective Member Country of the commercial exploitation is necessary to protect human or animal life or health or to avoid serious prejudice to plant life and the environment, provided that such exclusion is not made merely because the exploitation is prohibited or regulated by a legal or administrative provision;
c) plants, animals, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes;
d) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.

Article 21.- Products or processes already patented and included in the state of the art within the meaning of Article 16 of this Decision may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent.

CHAPTER II
On the Patent Owners

Article 22.- The right to a patent belongs to the inventor and may be assigned or transferred by succession.

Patent owners may be natural or judicial persons.

If several persons make an invention jointly, they shall share the right to patent it.

If several persons make the same invention, each independently of the others, the patent shall be granted to the person or assignee with the first filing date or, where priority is claimed, date of application.

Article 23.- Without prejudice to the provisions of national law in each Member Country, in the case of inventions made in the course of an employment relationship, the employer, whatever its form and nature, may transfer part of the economic benefits deriving from the innovations to the employee inventors in order to promote research activity.

Entities receiving state funding for their research shall reinvest part of the royalties received from the marketing of those inventions to generate a continuing supply of research funds and encourage researchers by giving them a share of the proceeds from the innovations, in accordance with the legislation in each Member Country.

Article 24.- The inventor shall have the right to be cited as such in the patent or to oppose being so mentioned.

CHAPTER III
On Patent Applications

Article 25.- A patent application may cover only one invention or a group of interrelated inventions that constitute a single inventive concept.

Article 26.- Applications for patents shall be filed with the competent national office and shall contain:

a) the petition;
b) the description;
c) one or more claims;

d) one or more drawings, if needed to understand the invention which, shall be considered an integral part of the description;
e) a summary;
f) such powers of attorney as may be needed;
g) proof of payment of the prescribed fees;
h) a copy of the contract for access, if the products or processes for which a patent application is being filed were obtained or developed from genetic resources or byproducts originating in one of the Member Countries;
i) if applicable, a copy of the document that certifies the license or authorization to use the traditional knowledge of indigenous, African American, or local communities in the Member Countries where the products or processes whose protection is being requested was obtained or developed on the basis of the knowledge originating in any one of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations;
j) the certificate of deposit of the biological material, if applicable; and,
k) a copy of the document attesting to the transfer of the patent right by the inventor to the applicant or assignee.

Article 27.- The patent application petition shall be a form that shall include the following information:

a) the application for a patent grant;
b) the applicant's name and address;
c) the nationality or address of the applicant and, should the applicant be a judicial person, the place of incorporation;
d) the name of the invention;
e) the name and address of the inventor, if a person other than the applicant;
f) the name and address of the applicant's legal representative, if pertinent;
g) the signature of the applicant or of the applicant's legal representative; and,
h) the date, number, and office of filing of any such application for a patent or other patent protection as may have been filed or obtained abroad by the applicant or assignee in respect of part or all of the same invention claimed in the application being filed in the respective Member Country, if pertinent.

Article 28.- The description of the invention shall be sufficiently clear and complete to be understood and for the invention to be carried out by a person skilled in the art. The description shall contain the name of the invention and the following information:

a) the technological sector to which the invention refers or in which it shall be applied;
b) prior technology known to the applicant that would help the invention to be understood and examined and references to previous documents and publications that discuss the technology involved;
c) a description of the invention in such a way that the technical problem and the solution provided by the invention may be understood, explaining the differences and possible advantages with respect to previos technology.
d) a brief description of the drawings if there are any;
e) a description of the best method known to the applicant for carrying out the invention, with the use of examples and references to the drawings if they are pertinent; and,
f) a statement as to how the invention meets the condition of being capable of industrial application, if this is not clear from the description or the nature of the invention itself.

Article 29.- Where the invention refers to a product or a process involving biological material and the invention cannot be understood and carried out, as described, by a person skilled in the art, it must be accompanied by a deposit of the said material.

The material shall be deposited by the filing date in the Member Country or, where priority is claimed, the date of application. Deposits with an international authority recognized under the 1977 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure or any other institution acknowledged by the competent national office as appropriate for this purpose shall be valid.

In such cases, the name and address of the depositary institution, the date of deposit, and the number assigned by that institution to the deposit shall be included in the description.

The deposit of biological material shall be valid for granting a patent only if it is carried out in such a way that any interested person may obtain samples of that material by the date of expiration of the period stipulated in article 40, at the latest.

Article 30.- Claims shall specify the subject matter for which patent protection is sought. They must be stated clearly and concisely and be fully substantiated by the description.

Claims may be independent or dependent. A claim shall be independent when it defines the subject matter in respect of which protection is sought without referring to any previous claim. A dependent claim, on the other hand, defines the subject matter for which protection is sought by referring to a prior claim. A claim referring to two or more previous claims is considered a multiple dependent claim.

Article 31.- The summary shall consist of a synthesis of the technical explanation given in the patent application. That summary shall be used to provide technical information only and shall have no effect whatsoever on the interpretation of the scope of protection conferred by the patent.

Article 32.- No Member Country may require the fulfillment of patent application requirements additional to or other than those set forth in this Decision.

Without prejudice to the foregoing, should the competent national office, during the processing of the application, have any reasonable doubts about any of the elements included, it may request the applicant to provide the necessary substantiating evidence.

Article 33.- The date of its receipt by the competent national office shall be considered the application filing date, providing that the application contained the following elements:

a) a statement that the applicant is applying for a patent;
b) data identifying the applicant or person filing the application or that shall enable the competent national office to communicate with that person;
c) a description of the invention;
d) the drawings, if pertinent; and,
e) the proof of payment of the prescribed fees.

Failure to comply with any of the requirements specified in this article shall cause the competent national office to reject the application for processing and no filing date shall be assigned to it.

Article 34.- The applicant for a patent may, at time during the processing, request the modification of the application, but that modification may not involve extending the scope of protection beyond the use indicated in the initial application.

The applicant may, likewise, request the correction of any material error.

Article 35.- Patent applicants may, at any time during the processing, request the conversion of their applications for an invention patent into applications for a utility model patent. That change in application shall be possible only if the nature of the invention permits that conversion.

An applicant may submit a petition for conversion of an application one time only. The converted application shall keep the original filing date.

The competent national offices may, at any stage of the processing, suggest that the applicant make a convertion in the patent being applied for and order an additional fee to be paid for filing the application for its conversion.

The applicant may accept or reject the suggestion on the understanding that if it is rejected the application shall continue to be processed as originally filed for.

Article 36.- Applicants may, at any time during the processing, divide their applications into two or more divisional applications, but none of these may have the effect of extending the scope of protection beyond the use indicated in the initial application.

The competent national office may, at any time during the process, ask the applicant to divide the application if it fails to comply with the requirement for the unity of the invention.
Each divisional application shall be entitled to keep the original filing date or, where priority is claimed, the initial date of application.

Where multiple or partial priorities are claimed, the applicant or the competent national office shall state what priority date or dates shall be applicable to the subject matters that each of these divisional applications shall cover.

For the purposes of the division of an application, the applicant shall file the necessary documents to complete each of the resulting applications.

Article 37.- The applicant may, at any moment during the processing, combine two applications into a single one, but this combination may not involve extending the scope of protection beyond the use indicated in the initial application.

No combination shall be permitted if the merged applications fail to comply with the requirement for the unity of the invention stipulated in article 25.

The combined application shall be entitled to keep the original filing date or, where priority is claimed, the initial date or dates of application.

CHAPTER IV
On the Processing of the Application

Article 38.- The competent national office shall examine the application within 30 days following its filing to ascertain whether it meets the conditions of form specified in articles 26 and 27.

Article 39.- If the examination of form reveals that the application does not fulfill the requirements referred to in articles 26 and 27, the competent national office shall request the applicant to complete those requirements within a period of two months following the date of notification. That period may be extended once, upon request, for an equal length of time without loss of priority.

If, on expiration of the specified period, the applicant has failed to comply with the required conditions, the application shall be considered abandoned and shall lose its order of preference. Without prejudice to this, the competent national office shall keep the information contained in the application confidential.

Article 40.- Within eighteen months after the filing date in the Member Country concerned or, where priority is claimed, after the date of application, the file shall assume a public nature and shall be open for consultation. The competent national office shall accordingly order the publication of that application in conformity with pertinent domestic provisions.

The applicant may request the publication of the application at any time after the examination of its form has been concluded, notwithstanding the stipulation of the previous paragraph. In that case, the competent national office shall order its publication.

Article 41.- A patent application file may not be consulted by third parties until the end of a period of eighteen months computed from its filing date, unless written consent has been obtained from the applicant.

Persons able to prove that the applicant for a patent has sought to assert against them rights deriving from that application may consult the file prior to publication without the consent of the said applicant.

Article 42.- Within a period of 60 days following the date of publication, any person with a legitimate interest may, one time only, submit valid reasons for contesting the patentability of the invention.

The competent national office shall grant once, upon request, a sixty-day extension in which to provide valid reasons for that opposition.

Reckless objections may be sanctioned if so stipulated by domestic law.

Article 43.- If any objections have been lodged, the competent national office shall request that the applicant present its arguments, submit documents, or rewrite the invention claims or description, as they see fit, within sixty days following that notification.

The competent national office shall grant applicants once only, upon request, a sixty-day extension in which to make their defense against the objections that have been presented.

Article 44.- The applicant shall request an examination be made of the patentability of the invention within six months after publication of the application, regardless of whether or not any objections have been filed. Member Countries may charge a fee for making the examination. If that period elapses without these applicant having requested the examination, their applications shall be considered to have been abandoned.

Article 45.- Were the competent national office to ascertain that their inventions are not patentable or fail to comply with any one of the requirements for granting patents stipulated in this Decision, it shall notify the applicants accordingly. These shall respond to that notification within sixty days after the date of notification. This period may be extended one time only for a period of thirty additional days.

The competent national office may notify applicants two or more times, pursuant to the preceding paragraph, should it deem such notifications necessary for its examination of the invention's patentability.

If those applicants fail to file an answer to the notification within the stipulated period or if, despite their explanations, the impediments to granting the patent continue to exist, the competent national office shall deny those patents.

Article 46.- The competent national office may request reports from experts or from scientific or technological bodies that are considered suitable, to get their opinions on the patentability of the invention. It may also, as it deems fit, request reports from other intellectual property offices.

If the examination of the patentability of the invention requires it, the applicant shall, at the request of the competent national office and within a period of no more than three months, submit one or several of the following documents connected with one or more foreign applications referring to all or part of the invention being examined:

a) a copy of the foreign application;
b) copies of the findings of the examinations of the novelty or patentability of the invention conducted with respect to the foreign application in question;
c) a copy of any patent or other patent protection that may have been granted on the basis of this foreign application;
d) a copy of any order or decision that may have been handed down rejecting or denying the foreign application; or,
e) a copy of any order or decision that may have been handed down annulling or invalidating the patent or other patent protection that was granted on the basis of the foreign application.

The competent national office may accept the results of the examinations referred to under letter b) as sufficient to certify that the conditions for the invention's patentability have been fulfilled.

If the applicant fails to submit the documents that have been requested within the period stipulated in this article, the competent national office shall deny the patent.

Article 47.- The competent national office may, at the request of the applicant, suspend the processing of the patent application if any one of the documents that are to be submitted pursuant to article 46 b) and c) has not yet been obtained by the applicant or is presently being processed by a foreign authority.

Article 48.- If the findings of the final examination are favorable, the patent shall be granted. If they are partially unfavorable, the patent shall be granted only in respect of those claims that have been accepted. If they are entirely unfavorable, the patent shall be denied.

Article 49.- For organizing and classifying their patents, the Member Countries shall use the International Patent Classification established by the 1971 Strasbourg Agreement Concerning the International Patent Classification, together with its effective amendments.

CHAPTER V
On the Rights conferred by Patents

Article 50.- Patents shall have a term of twenty years counted from the filing date of the corresponding application in the Member Country.

Article 51.- The scope of the protection conferred by a patent shall be determined by the wording of the claims. The description and drawings, or the deposit of biological material where applicable, shall be used for the interpretation of the claims.

Article 52.- A patent shall confer on its owner the right to prevent third parties not having the owner's consent from the acts of:

a) where the subject matter of a patent is a product:
i) making the product;
ii) offering for sale, selling, or using the product; or importing it for these purposes; and,
b) where the subject matter of a patent is a process:
i) using the process; or,
ii) carrying out any of the acts that are specified under paragraph a) above with respect to a product obtained directly by that process.

Article 53.- A patent owner may not exercise the right referred to in the previous article with respect to the following acts:

a) acts carried out in a private circle and for non-commercial purposes;
b) acts carried out exclusively to experiment with the subject matter of the patented invention;
c) acts carried out exclusively for the purposes of teaching or scientific or academic research;
d) the acts referred to in article 5bis of the Paris Convention for the Protection of Industrial Property;
e) where the patent protects biological material that is capable of being reproduced, except for plants, using that material as a basis for obtaining a viable new material, except where the patented material must be used repeatedly to obtain the new material.

Article 54.- A patent shall not confer on its owner the right to proceed against a third party making commercial use of a product protected by a patent once that product has been introduced into the commerce of any country by the owner or another person authorized by the right holder or with economic ties to that patent owner.

For the purposes of the preceding paragraph, two persons shall be considered to have economic ties when one of the persons is able to exercise a decisive influence on the other, either directly or indirectly, with respect to the exploitation of the patent or when a third party is able to exert that influence over both persons.

Where the patent protects biological material that is capable of being reproduced, the patent coverage shall not extend to the biological material that is obtained by means of the reproduction, multiplication, or propagation of the material that was introduced into the commerce as described in the first paragraph, provided that it was necessary to reproduce, multiply, or propagate the material in order to fulfill the purposes for which it was introduced into commerce and that the material so obtained is not used for multiplication or propagation purposes.

Article 55.- Without prejudice to the provisions stipulated in this Decision with respect to patent nullity, the rights conferred by a patent may not be asserted against a third party that, in good faith and before the priority date or the filing date of the application on which the patent was granted, was already using or exploiting the invention, or had already made effective and serious preparations for such use or exploitation.

In such case, the said third party shall have the right to start or continue using or exploiting the invention, but that right may only be assigned or transferred together with the business or company in which that use or exploitation is taking place.

Article 56.- A patent grant or a patent application being processed may be assigned or transferred by succession.

Any patent assignment or transfer shall be registered with the competent national office. Failure to register shall render the assignment or transfer invalid with respect to third parties.

Patent assignments or transfers, in order be registered, shall be in writing.

Any interested party may file for registration of a patent assignment or transfer.

Article 57.- The owner of a patent or of a patent application that is being processed may license one or more third parties to exploit the invention it covers.

Any license that is granted for the exploitation of a patent shall be registered with the competent national office. Failure to register shall render the license invalid with respect to third parties.

Licenses, in order to be registered, shall be in writing.

Any interested party may file for registration of a license.

The registered patent owner shall inform the competent national office about any change in the name or address of the right holder during the term of the license contract. Otherwise, any notification that may be made on the basis of the data entered in the registry shall be considered valid.

Article 58.- The competent national authority shall not register any license agreements for patent exploitation that do not conform to the provisions of the Common Regime for the Treatment of Foreign Capital and for Trademarks, Patents, Licenses, and Royalties, or that do not conform to Andean Community or domestic antitrust provisions.

CHAPTER VI
On the Obligations of the Patent Owner

Article 59.- Owners of patents shall be under the obligation to exploit their patented inventions in any Member Country, either directly or through a person they authorize to do so.

Article 60.- For the purposes of this Chapter, exploitation shall be understood to mean the industrial manufacture of the patented product or the full use of the patented process, including the distribution and marketing of the results thereof on a scale sufficient to satisfy the demands of the market. Exploitation shall also be understood to mean the importation of the patented product, including its distribution and marketing, where this is done on a scale sufficient to satisfy the demands of the market. Where the patent refers to a process that does not result in a product, the requirements for marketing and distribution shall not be enforced.

CHAPTER VII
On the Regime of Compulsory Licensing

Article 61.- At the expiry of a period of three years following a patent grant or of four years following the application for a patent, whichever is longer, the competent national office may grant a compulsory license mainly for the industrial manufacture of the product covered by the patent, or for full use of the patented process, at the request of any interested party, but only if, at the time of the request, the patent had not been exploited in the manner specified in articles 59 and 60, in the Member Country in which the license is sought, or if the exploitation of the invention had been suspended for more than one year.

Compulsory licenses shall not be granted if patent owners are able to give valid reasons for their failure to act, which may be reasons of force majeure or an act of God, in accordance with the domestic provisions in effect in each Member Country.

A compulsory license shall be granted only if, prior to applying for it, the proposed user has made efforts to obtain a contractual license from the patent holder on reasonable commercial terms and conditions and that such efforts were not successful within a reasonable period of time.

Article 62.- Decisions to grant a compulsory license, as stipulated in the previous article, shall be taken after the patent owners have been notified to present their arguments as they see fit within the following sixty days.

The competent national office shall specify the scope or coverage of the license, and in particular shall specify the period for which it is granted, the subject matter of the license, the amount of the remuneration, and the conditions for the payment thereof. The remuneration shall be set at an adequate level in accordance with the individual circumstances of each case and, in particular, the economic value of the authorization.

Opposition to a compulsory license shall not prevent its exploitation or have any effect on any periods that may be running. The filing of an objection shall not prevent the patent owner, in the meantime, from collecting the remuneration specified by the competent national office on the part unaffected by the objection.

Article 63.- At the request of the owner of the patent or the licensee, the conditions governing the compulsory license may be changed by the competent national office where new circumstances so dictate and, in particular, when the patent holder grants another license on terms that are more favorable than the existing ones.

Article 64.- The licensee shall exploit the licensed invention within a period of two years following the date the license was granted, unless that licensee is able to give valid reasons for inaction consisting of force majeure or an act of God. Otherwise, at the patent owner's request, the competent national office shall revoke the compulsory license.

Article 65.- Following the declaration by a Member Country of the existence of public interest, an emergency, or national security considerations, and only for so long as those considerations exist, the patent may be subject to compulsory licensing at any time. In that case, the competent national office shall grant the licenses that are applied for. The owner of the patent so licensed shall be notified as soon as is reasonably possible.

The competent national office shall specify the scope or extent of the compulsory license and, in particular, the term for which it is granted, the subject matter of the license, and the amount of remuneration and the conditions for its payment.

The grant of a compulsory license for reasons of public interest shall not reduce the right of the patent owner to continue exploiting it.

Article 66.- The competent national office may, either ex officio or at the request of a party, and after having obtained the consent of the national antitrust authority, grant compulsory licenses where practices are noted that are detrimental to the exercise of free competition, especially where they constitute an abuse by the patent owner of a dominant position in the market.

The need to correct anti-competitive practices shall be taken into account in determining the amount of remuneration to be paid in such cases.

The competent national office shall refuse termination of a compulsory license if and when the conditions which led to the granting of the license are likely to recur.

Article 67.- The competent national office shall grant a license, upon request by the owner of a patent whose exploitation necessarily requires the use of another patent, and that right holder has been unable to secure a contractual license to the other patent on reasonable commercial terms. That license shall, without prejudice to the provisions of article 68, be subject to the following conditions:

a) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
b) the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and,
c) the license authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 68.- In addition to the conditions provided for in the preceding articles, compulsory licenses shall be subject to the following:

a) they shall be non-exclusive and may not be sublicensed;
b) they shall be non-assignable, except with the part of the business or goodwill which permits its industrial use. This shall be evidenced in writing and registered with the competent national office. Otherwise, those assignments or transfers shall not be legally binding;
c) they shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to them cease to exist and are unlikely to recur;
d) their scope and duration shall be limited to the purposes for which they were authorized;
e) in the case of patents protecting semi-conductor technology, a compulsory license shall be authorized only for public non-commercial use or to remedy a practice declared by the competent national authority to be anti-competitive in accordance with articles 65 and 66;
f) they provide for payment of adequate remuneration according to the circumstances of each case, taking into account the economic value of the license, without prejudice to the stipulations of article 66; and,
g) they shall be used predominantly for the supply of the domestic market.

Article 69.- Compulsory licenses that fail to comply with the provisions of this Chapter shall be devoid of any legal effect whatsoever.

CHAPTER VIII
On Acts Subsequent to the Grant

Article 70.- A patent owner may request the competent national office to modify the patent in order to enter any change in the name, address, residence or other information about the rights holder or the inventor or to amend or limit the scope of one or more of the claims. The owner of the patent may, likewise, request that any material error in the patent be rectified.

The provisions in respect of the modification or correction of an application shall be applicable as pertinent.

Article 71.- The owner of a patent may, through a declaration addressed to the competent national office, withdraw one or more patent claims or a claim to the patent as a whole. That withdrawal shall become effective as of the date the respective declaration is received.

Article 72.- The owner of a patent may divide it into two or more fractional patents. The provisions regarding the division of an application shall be applicable to that of patents, in all pertinent matters.

Article 73.- A patent owner may also combine two or more patents. The provisions regarding the combination of applications shall be applicable to these patents, in all pertinent matters.

Article 74.- The competent national office may establish the fees on acts carried out after the patent grant.

CHAPTER IX
On the Invalidation of the Patent

Article 75.- The competent national authority may, either ex officio or at the request of a party, and at any time, declare a patent null and void, where:

a) the subject matter of the patent is not an invention according to the requirements stipulated in article 15;
b) the invention fails to comply with the requirements for patentability set out in article 14;
c) the patent was granted for an invention covered by article 20;
d) the patent fails to disclose the invention, as required by article 28 and, if pertinent, article 29;
e) the claims included in the patent are not fully substantiated by the description provided;
f) use of the patent granted has been broader than was indicated in the original application and requires having to extend its scope of protection;
g) when pertinent, the products or processes in respect of which the patent is being filed have been obtained and developed on the basis of genetic resources or their byproducts originating in one of the Member Countries, if the applicant failed to submit a copy of the contract for access to that genetic material;
h) when pertinent, the products or processes whose protection is being requested have been obtained or developed on the basis of traditional knowledge belonging to indigenous, African American, or local communities in the Member Countries, if the applicant has failed to submit a copy of the document certifying the existence of a license or authorization for use of that knowledge originating in any one of the Member Countries; or,
i) there are grounds for absolute invalidation according to domestic legislation covering administrative acts.

Where the grounds specified above are applicable only to some of the claims or some parts of a claim, invalidation shall be pronounced only in respect of those claims or those parts of the said claim, as the case may be.

The patent, claim, or part of a claim that has been invalidated shall be deemed null and void as from the filing date of the patent application.

Article 76.- Where defects in administrative acts fail to produce absolute invalidation as specified in the preceding article, those acts shall be relatively invalidated. In such cases, the competent national authority shall, in conformity with domestic legislation, declare them null and void within a period of five years counted from the patent grant date.

Article 77.- The competent national authority may, where a patent has been granted to a person who has no right to it, annul that patent. Invalidation proceedings may be initiated only by the person who has a right to obtain that patent. That right of action shall lapse five years after the patent grant date or two years following

the date on which the person to whom that right belongs learned about the use of the invention, whichever period expires first.

Article 78.- In invalidation proceedings, the competent national authority shall request the patent owners to present arguments and submit the proof they deem advisable.

Where that authority under the domestic law of a Member Country is the competent national office, the patent owner shall present the arguments and submit the proof referred to in the previous article within a period of two months after being notified thereof.

Before the expiry of the period stipulated in the previous article, the interested party may request an extension of two additional months.

Once the periods stipulated in this article have expired, the competent national office shall rule on the patent's invalidation and inform the parties of its decision.

Article 79.- The competent national authority may, where necessary to rule on the invalidation of a patent, request the patent owner to submit one or more of the documents referred to in article 46 with regard to the patent that is the subject matter of the proceeding.

CHAPTER X
On the Lapsing of the Patent

Article 80.- Annual fees prescribed by the competent national offices shall be paid in advance in order to keep a patent in force or to maintain a pending patent application, as the case may be.

The deadline for payment of each annual fee shall be the last day of the month of presentation of the invoice. Two or more annual fees may be paid in advance.

Annual fees shall be paid within a grace period of six months after the starting date of the corresponding annual period, together with the prescribed surcharge. The patent or pending application shall remain in full force during the grace period.

Failure to pay an annual fee as stipulated in this article shall result in the legal lapsing of the patent or the patent application.

TITLE III
ON UTILITY MODELS

Article 81.- Any new shape, configuration, or arrangement of components of any device, tool, implement, mechanism or other object, or any part thereof, that permits improved or different operation, use, or manufacture of the object incorporating it, or that endows it with any utility, advantage, or technical effect that it did not have previously shall be considered a utility model.

Utility models shall be protected by patents.

Article 82.- The following shall not be considered utility models: sculptures, architectural works, or objects that are purely aesthetic in nature.

Processes and materials excluded from patent protection may not be the subject matter of utility model patents.

Article 83.- An applicant for a utility model patent may request its conversion into an invention patent or registration of an industrial model, provided that the subject matter of the original application so permits. In the latter case, it shall be necessary to fulfill the requirements stipulated in article 35.

Article 84.- The duration of the utility model shall be ten years, as of the application filing date in the Member Country concerned.

Article 85.- The provisions of this Decision in respect of invention patents shall be applicable to utility model patents, as pertinent. The only exceptions are the processing periods, which shall be reduced to one-half their length. Without prejudice to the foregoing, the period stipulated in article 40 shall be shortened to twelve months.

TITLE IV
ON THE LAYOUT-DESIGNS (TOPOGRAPHIES) OF INTEGRATED CIRCUITS

CHAPTER I
Definitions

Article 86.- The following definitions shall apply for purposes of this Title:

a) integrated circuit: a product, in final or intermediate form, of which at least one element is an active element and some or all of whose interconnections are an integral part of the body or surface of a piece of material that is intended to be used electronically;
b) layout-design: the three-dimensional arrangement of the elements, regardless of form, of which at least one is an active element, and their interconnection into an integrated circuit, as well as that three-dimensional arrangement prepared for use in an integrated circuit to be manufactured.

CHAPTER II
On the Requirements for Protection of Layout-Designs of Integrated Circuits

Article 87.- A layout-design shall be protected if it is an original design.

A lay-out design shall be considered original when it is the result of its creator's intellectual efforts and is not in common use in the integrated circuit industry.

Where composed of two or more elements in common use in the integrated circuit industry, a layout-design shall be considered original only if the combination of those elements, as an assembly, meets this requirement.

CHAPTER III
On the Right Holders

Article 88.- The right to register a layout-design of an integrated circuit belongs to its designer. That right may be assigned or transferred by succession.

If two or more persons jointly prepare a layout-design, those persons shall share the right to protect it.

The right to protection of a layout-design created under a project or service contract entered into for this purpose or within the framework of an employment relationship in wich the designer has such function, shall correspond to the person who contracted for the project or service, or the employer, unless otherwise stipulated under a contract.

CHAPTER IV
On the Application for Registration

Article 89.- The application to register a layout-design of an integrated circuit shall be filed with the competent national office and shall contain the following information:

a) the petition;
b) a copy or drawing of the layout-design and, if commercially exploited, a sample of that integrated circuit;
c) if pertinent, a statement of the date of first commercial exploitation of the integrated circuit anywhere in the world;
d) if pertinent, the statement of the year the integration circuit was created;
e) a description of the electronic operation to be performed by the integrated circuit in the layout-design;
f) copies of any applications for registration or other protection filed for or obtained abroad by the applicants or their assignees, referring to all or part of the layout-design for which a registration application is being filed in the Member Country;
g) such powers of attorney as may be needed; and,
h) a proof of payment of the prescribed fee.

Article 90.- The petition to register an application for a layout-design of an integrated circuit shall be a form and shall include the following information:

a) the request for the registration;

b) the name and address of the applicant;
c) the nationality or address of the applicant and, if the applicant is a juridical person, the site of incorporation;
d) the name and address of the creator of the layout-design, if a person other than the applicant;
e) the name and address of the applicant's legal representative, if pertinent;
f) the date, number, and office where any other application for registration or other protection was filed or obtained abroad by the applicant or assignee in respect of all or part of the same layout design being applied for in the Member Country, if pertinent; and,
g) the signature of the applicant or the applicant's legal representative.

Article 91.- Where the layout-design for which a registration application has been filed includes an industrial secret, the applicant shall file, in addition to the graphic representation required, a representation of the layout omitting, erasing, or distorting the parts containing that secret. It is necessary for the remaining parts to be sufficient to allow for identification of the layout-design.

Article 92.- The date of reception of an application by the competent national office shall be considered its filing date, provided that the application contained at least the following elements:

a) an express or implicit statement that the application is being filed for the registration of a layout-design;
b) data that shall permit identification of the applicant or person filing the application or enable the competent national office to communicate with that person;
c) a graphic representation of the layout-design for which registration is being applied for; and
d) the proof of payment of the prescribed fees.

Failure to comply with any one of the requirements specified in this article shall result in refusal by the competent national to process the application and no filing date shall be assigned to it.

CHAPTER V
On the Processing of the Application

Article 93.- The competent national office shall examine whether the subject matter of the application constitutes a layout-design as defined in article 86 and whether the application contains the information requested in articles 89, 90, and 91. The competent national office shall not examine the originality of the layout-design ex officio, unless reasoned opposition to the application has been presented.

Should any omission or defect be noted, the applicant shall be admonished to make the necessary correction within a period of three months, and that failure to do so shall be considered abandonement and shall be placed in the archives ex officio. If the applicant does not make the correction within the allotted period, the competent national office shall make that warning effective through a reasoned decision.

Article 94.- Having examined the application, the competent national office shall order its announcement through the publication in the official government gazette of a notice to be paid by the interested party.

The pertinent provisions in respect of applications for investment patents shall be applicable to the publication of the notice.

Article 95.- Any interested person may lodge a substantiated objection with the competent national office, including information and documents that would be useful for ascertaining the registerability of a layout-design.

Pertinent provisions in respect of applications for invention patents shall be applicable to the objections.

Article 96.- If the stipulated requirements are fulfilled, the competent national office shall register the layout design and issue a registration certificate containing the data included in the corresponding registry.

CHAPTER VI
On the Rights conferred by Registration

Article 97.- If the layout-design has been exploited commercially anywhere in the world, the application for registration shall be filed with the competent national office of the Member Country concerned within a period of two years from its first commercial exploitation. If the application is filed after the expiration of that period, the registration shall be denied.

A layout-design not having been commercially exploited anywhere in the world may be registered only if applied for to a competent national office of a Member Country no later than 15 years after the last day of the year the layout was created. If the application is filed after that period has expired, its registration shall be denied.

Article 98.- Exclusive rights over a registered layout-design shall have a duration of ten years from the oldest of the following dates:

a) the last day of the year the layout-design was first commercially exploited anywhere in the world, or
b) the filing date of an application for registration with the competent national office of the Member Country concerned.

The term of protection of a registered layout-design shall lapse in any case at the conclusion of a period of 15 years counted from the last day of the year in which the layout-design was created.

Article 99.- The protection shall be applied irrespective of whether the integrated circuit in which the protected layout-design has been incorporated has been manufactured and irrespective of whether the layout-design has been incorporated into an integrated circuit.

Registration of a layout-design of an integrated circuit confers on its holder the right to impede third persons from performing any of the following acts:

a) reproducing, through incorporation into an integrated circuit or in any other way, all or part of the protected layout-design that complies with the requirements for originality stipulated in article 87;
b) marketing, importing, offering for sale, selling, or otherwise distributing a protected layout-design or an integrated circuit in which a protected layout-design is incorporated; or
c) marketing, importing, offering for sale, selling, or otherwise distributing an article incorporating such a protected integrated circuit, only insofar as it continues to contain an unlawfully reproduced layout-design.

Protection conferred by registration shall cover only the layout-design itself, and shall not extend to any idea, process, system, technique, or data encoded or incorporated into the layout-design.

Article 100.- The right conferred by registration of the layout-design only may be asserted against acts having industrial or commercial purposes. Registration shall not confer the right to impede the following acts:

a) acts carried out in a private circle and for non-commercial purposes;
b) acts carried out exclusively for purposes of evaluation, analysis, or experimentation;
c) acts carried out exclusively for purposes of teaching or scientific or academic research;
d) acts referred to in article 5 of the Paris Convention for the Protection of Industrial Property.

Article 101.- Registration of a layout-design shall not give the holder the right to prevent third parties from engaging in acts of commerce in respect of registered layout-designs, integrated circuits in which a protected layout-design is incorporated, or articles containing those integrated circuits after the introduction of the layout-design into the commerce of any country by the right holder or by any other person with the consent of or having economic ties to that right holder.

For purposes of the preceding paragraph, two persons shall be considered to have economic ties when one of the persons is able to exercise a decisive influence over the other, either directly or indirectly, with respect to exploitation of the layout-design, or when a third party is able to exert that influence over both persons.

Article 102.- The right holder to a registered layout-design may not prevent a third party from engaging in acts of industrial or commercial exploitation in respect of a layout-design created by another person through the evaluation or analysis of the protected layout-design, where the layout-design thereby created fulfills the requirements for originality stipulated in Article 87. Nor may that right holder prevent those acts in respect of integrated circuits in which the layout-designs so created are incorporated or of articles incorporating those integrated circuits.

Article 103.- The right holder of a registered layout-design may not prevent a third party from carrying out the acts cited in article 99 with respect to another layout-design originally created by a third party, even if identical.

Article 104.- Performance of any of the acts referred to in article 99 in respect of an integrated circuit incorporating an unlawfully reproduced layout-design or any article incorporating such an integrated circuit shall not be considered an infringement of rights to a registered design, where the person performing or ordering such acts did not know and had no reasonable ground to know, when acquiring the integrated circuit or article incorporating such an integrated circuit, that it incorporated an unlawfully reproduced layout-design. After the time that such person has received sufficient notice that the layout-design was unlawfully produced, that person may continue to perform any of the acts with respect to the stock on hand or ordered before such time, but shall be liable to pay the right holder a sum equivalent to a reasonable royalty such as would be payable under a freely negotiated license in respect of such layout-design.

Article 105.- A layout-design registration that has been granted or is being processed may be assigned or transferred by succession.

Any assignment or transfer of a layout-design registration shall be filed with the competent national office. Failure to register that assignment or transfer shall render it legally invalid in respect of third parties.

Assignments or transfers, in order to be registered, shall be in writing.

Any interested person may apply for registration of an assignment or transfer.

CHAPTER VII
On the Licensing System

Article 106.- The right holder for a layout-design that is registered or for which registration has been filed may license one or more parties to exploit that lay-out design.

Any license to use the layout-design shall be registered with the competent national office. Failure to register the license shall render it invalid with respect to third parties.

Licenses, in order to be registered, shall be in writing.

Any interested party may file for registration of a license.

The registered right holder shall inform the competent national office of any change in the name or address of the registered layout-design right holder during the term of the licensing contract. Otherwise, any notification that may be made on the basis of the data entered in the registry shall be considered valid.

Article 107.- The competent national authority may, given a lack of exploitation or for reasons of public interest, in particular a national emergency, or for public health or natural security considerations, or to remedy an anti-competitive practice, and at the request of an interested party or of a competent authority, order the following at any time:

a) that layout-designs that are registered or for which registration has been filed shall be used or exploited industrially or commercially by a government institution or by one or more public or private legal entities that have been expressly appointed to do so; or
b) that the said layout-design shall be subject to the granting of one or more compulsory licenses, in which case the competent authority may grant such a license to any person who applies for it, subject to the conditions that have been stipulated for that purpose.

The conditions that have been stipulated for granting compulsory licenses with respect to invention patents shall be applicable to the granting of a compulsory licenses in regard to a layout-design.

CHAPTER VIII
On the Invalidation of the Registration

Article 108.- The competent national authority may, either ex officio or at the request of a party and at any time, declare the registration of a layout-design null and void, where:

a) the subject matter of the registration is not a layout-design according to the requirements stipulated in article 86;
b) the registration fails to comply with the requirements for protection set forth in article 87;
c) the registration was granted for a layout design applied for after the expiration of one of the periods established in article 97; or,

d) there are grounds for declaring the registration to be null and void according to domestic legislation covering administrative acts.

Where the grounds specified above are applicable to only a part of the layout-design, invalidation shall be pronounced only in respect of that part, as pertinent, leaving the registration valid for the other parts, provided that as a whole the layout-design complies with the requirements for originality stipulated in article 87.

The layout-design or the part of it that has been invalidated shall be deemed null and void as of the filing date of the application for its registration.

Article 109.- Where defects in administrative acts fail to produce absolute invalidation as specified in the preceding article, those acts shall be invalidated relatively. In such cases, the competent national authority may, in conformity with domestic legislation, declare them null and void within a period of five years counted from the date of registration.

Article 110.- The competent national authority may, where a layout- design registration has been granted to a person that has no right to it, annul that registration. The invalidation proceeding may be brought only by the person with a right to registration of that layout-design. That right of action shall lapse five years from the date the registration was granted or two years following the date on which the person to whom that right belongs learned about the marketing in the Member Country of the product incorporating that layout-design, whichever period expires first.

Article 111.- In invalidation proceedings, the competent national authority shall request registered right holders to present their arguments and submit the proof they deem advisable.

Where that authority, under the domestic law of a Member Country, is the competent national office, the registered right holder shall present the arguments and submit the proof referred to in the previous article within a period of two months following notification.

Before the expiration of the period stipulated in the previous article, the interested party may request an extension of two additional months.

Once the periods stipulated in this article have expired, the competent national office shall rule on the invalidation of the registration and notify the parties of its decision.

Article 112.- The competent national authority may, where necessary to rule on the invalidation of a registration, request the right holder to submit one or more of the documents referred to in article 89 with regard to the registration that is the subject matter of the proceeding.

TITLE V
ON INDUSTRIAL DESIGNS

CHAPTER I
On Requirements for Protection

Article 113.- The particular appearance of a product that results from any arrangement of lines or combination of colors, or any two-dimensional or three-dimensional outward shape, line, outline, form, texture, or material, without the intended use or purpose of the said product being thereby changed, shall be considered an industrial design.

Article 114.- The right to register an industrial design belongs to the designer and may be assigned or transferred by succession.

Registration right holders may be natural persons or legal entities.

If several persons make an industrial design jointly, they shall share the right to its registration.

If several persons make the same industrial design, each independently of the others, registration shall be granted to the person or assignee with the first filing date or, where priority is claimed, date of application.

Article 115.- Industrial designs that are new shall be registrable.

An industrial design shall not be considered new if, before the filing date or validly claimed priority date, it has been made accessible to the public in any place or at any time, by description, use, or any other means.

An industrial design shall not be new by virtue of the mere fact that it embodies secondary differences in relation to earlier creations, or that it refers to a category of products different from that to which the said creations belong.

Article 116.- The following creations shall not be registrable:

a) industrial designs when, the prevention of the commercial exploitation of which within the territory of the Member Country where registration is being applied for, is necessary to protect morality or public order. To those ends, commercial exploitation of an industrial design shall not be considered contrary to morals and public order merely by reason that the exploitation is prohibited or regulated by a legal or administrative provision;
b) industrial designs the appearance of which was dictated essentially by technical or functional considerations and that fail to incorporate any arbitrary contribution by the designer; and,
c) industrial designs that consist only of a form the exact reproduction of which proved necessary in order to permit the mechanical assembly or connection of the product incorporating the design with another product of which it is a part. This prohibition shall not be applicable to products in which the design consists of another way to permit the assembly or the multiple connection of the product or of its connection within a modular system.

CHAPTER II
On the Registration Procedure

Article 117.- An application to register an industrial design shall be filed with the competent national office and shall contain the following:

a) the petition;
b) a graphic or photographic representation of the industrial design. This representation, in the case of two-dimensional designs incorporated onto a flat material, may be replaced by a sample of the product incorporating the design;
c) such powers of attorney as may be needed;
d) proof of payment of the prescribed fees;
e) a copy of the document recording the ceding or transfer to the applicant of the right to register the industrial design, if applicable; and,
f) copies of any applications for registration or other protection of an industrial design filed abroad by the applicant or assignee in respect of the same design for which a registration application or claim is being filed in the respective Member Country.

Article 118.- The petition for the industrial design registration application shall be a form and shall include the following information:

a) the request for registration of the industrial design;
b) the name and address of the applicant;
c) the nationality address of the applicant and, if the applicant is a legal entity, the site of incorporation;
d) an indication of the kind or type of product to which the design shall be applied and the category and sub-category of such products;
e) the name and address of the designer, if other than the applicant;
f) the date, number, and identification of the office where any applications for registration or other protection of an industrial design were filed or obtained abroad by the applicant or assignee in respect of the same design claimed in the application being filed in the respective Member Country, if applicable;
g) the name and address of the applicant's legal representative, if pertinent; and,
h) the signature of the applicant or the applicant's legal representative.

Article 119.- The date of its receipt by the competent national office shall be considered the application filing date, provided that the application contained at least the following elements:

a) a statement that the applicant is filing for the registration of an industrial design;
b) data identifying the applicant or person filing the application that will enable the competent national office to communicate with that person;

c) a graphic or photographic representation of the industrial design. This representation, in the case of two-dimensional designs incorporated onto a flat material, may be replaced by a sample of the product incorporating the design; and,
d) a proof of payment of the prescribed fees.

Failure to comply with any of the requirements specified in this article shall cause the competent national office to reject the application for processing and no filing date shall be assigned to it.

Article 120.- The competent national office shall examine the application within 15 days following the filing to ascertain whether it meets the terms and conditions conditions of form specified in articles 117 and 118.

If the examination of terms and conditions reveals that the application does not fulfill the requirements referred to in the preceding paragraph, the competent national office shall notify the applicant to complete those requirements within a period of thirty days following the date of notification. The said period may be extended once, upon request, for an equal length of time without loss of priority.

If, on expiration of the specified period, the applicant has failed to comply with the required conditions, the application shall be considered abandoned and shall lose its order of priority. Without prejudice to this, the competent national office shall maintain the information contained in the application confidential.

Article 121.- If the application fulfills the stipulated requirements, the competent national office shall order its publication.

Article 122.- Within a period of thirty days following the date of publication, any person with a legitimate interest may, one time only, present valid reasons for contesting the registration of industrial design.

The competent national office shall grant such persons once, upon request, an additional period of thirty days in which to present valid reasons for their opposition.

Reckless objections may be sanctioned if so stipulated by domestic legislation.

Article 123.- If any objections have been lodged, the competent national office shall request that the applicants present their arguments or submit documents, as they see fit within thirty days following that notification.

The competent national office shall, upon request, grant an additional period of thirty days in which to make a defense against the objections that have been raised.

Article 124.- Upon expiration of the period stipulated in the preceding article or should no objections have been raised, the competent national office shall conduct an examination to ascertain whether the subject matter of the application complies with the requirements established in articles 113 and 116.

The competent national office shall not make an examination ex officio of the novelty of the subject matter of the application if no valid reasons are presented based upon the existence of a prior right or the novelty of the industrial design.

Without prejudice to the foregoing, if the lack of novelty of an industrial design is glaringly obvious, the competent national office shall reject the application ex officio.

Article 125.- An application for registration of an industrial design may not be consulted by third parties until publication has been ordered at the conclusion of the stipulated period, except where written consent has been obtained from the applicant.

Any parties who prove that the application for registration of an industrial design is attempting to use against them of rights conferred on the applicant for registration of an industrial design by the said application may consult the file before its publication without the consent of the applicant.

Article 126.- The competent national office shall grant the registration of the industrial design and issue the corresponding certificate to the rights holder upon fulfillment of the stipulated requirements. Failure to comply with those requirements shall cause the competent national office to reject the application.

Article 127.- Member Countries shall use the International Classification for Industrial Designs established by the Locarno Agreement of October 8, 1968 and its effective amendments to organize and classify industrial designs.

CHAPTER III
On the Rights conferred by Registration

Article 128.- Registration of an industrial design shall be for a term of ten years, counted from the filing of the application in the Member Country.

Article 129.- Registration of an industrial design shall confer on the owner thereof the right to prevent third parties from making use of the design concerned. By virtue of that prohibition, the owner of the registration shall be entitled to proceed against any third party who, without the consent of the right holder, manufactures, imports, offers for sale, markets, or makes commercial use of products that incorporate or reproduce the industrial design.

Registration shall likewise confer the right to proceed against any person who produces or markets an article whose design only presents minor differences with respect to the protected design or where appearence is the same as the latter protected design.

Article 130.- The protection accorded to an industrial design shall not apply to elements or characteristics of the design dictated essentially by technical or functional considerations or that fail to incorporate any arbitrary contribution by the designer.

The protection accorded to an industrial design shall not apply to the exact reproduction of such elements or characteristics as may be needed to allow the product incorporating the design to be mechanically assembled or joined to another product of which it is a part. This restriction shall not apply where the design assumes a particular form to allow for the assembly or multiple connections of the products or the connection of those products within a modular system.

Article 131.- Registration of an industrial design shall not confer the right to proceed against a third party who makes commercial use of a product incorporating or reproducing the design once it has been introduced into the commerce of any country by the right holders or another person authorized by them or with economic ties to those right holders.

For purposes of the preceding paragraph, two persons shall be considered to have economic ties when one of the persons is able to exercise a decisive influence over the other, either directly or indirectly, with respect to the exploitation of the industrial design, or when a third party is able to exert that influence over both persons.

Article 132.- The competent national authority may, either ex officio or at the request of a party and at any time, declare the registration of an industrial design null and void, when:

a) the subject matter of the registration is not an industrial design according to the requirements established in article 113;
b) the industrial design fails to comply with the requirements for protection set forth in article 115;
c) the registration was granted for subject matter that is excluded from protection by the stipulations of article 116; or,
d) there are grounds for declaring the registration null and void according to domestic legislation covering administrative acts.

Article 133.- The provisions stipulated in articles 17, 34, 53 paragraphs a), b), c) and d), 56, 57, 70, 74, 76, 77, 78, and 79 shall be applied in respect of industrial designs.

TITLE IV
ON TRADEMARKS

CHAPTER I
On Registration Requirements

Article 134.- For purposes of this system, any sign that is capable of distinguishing goods and services on the market shall constitute a trademark. Signs that are capable of graphic representation shall be eligible for

registration as trademarks. The nature of the goods or services to which a trademark is to be applied shall in no case form an obstacle to the registration of the trademark.

The following signs, among others, shall be capable of constituting a trademark:

a) words or a combination of words;
b) pictures, figures, symbols, graphic elements, logotypes, monograms, portraits, labels, and emblems;
c) sounds and smells;
d) letters and numbers;
e) a color demarcated to give it a specific shape, or a combination of colors;
f) the shape of a product its packaging or wrappings;
g) any combination of the signs or means indicated in the items above.

Article 135.- Signs may not be registered as trademarks when they:

a) fail to constitute a trademark according to the requirements stated in the first paragraph of the previous article;
b) are lacking in distinguishable characteristics;
c) consist solely of the everyday shape of goods or their packaging, or of shapes or characteristics dictated by the nature or particular function of the product or service in question;
d) consist exclusively of shapes or other elements that attribute a functional or technical advantage to the product or service to which they are applied;
e) consist solely of a sign or statement that may serve in commerce to designate or describe, in respect of the goods or services for which they are to be used, their quality, quantity, purpose, value, geographical origin, or time of production, or that impart other details, characteristics, or information, including expressions of praise for those goods or services;
f) consist exclusively of a sign or statement that is the common or technical name of the product or service concerned;
g) consist solely of or have become a sign or statement which, in everyday language or normal use within the country, is the common or usual designation for the goods or services in question;
h) consist of a color in isolation, without any demarcation to give it a specific shape;
i) are liable to create confusion in business circles or the public, in particular as to the geographical origin, nature, manufacturing methods, characteristics, or qualities of the goods or services concerned, or their suitability for use;
j) reproduce, imitate, or contain a protected indication of origin that is liable to create confusion or a mistaken association with the indication in relation to the goods themselves or different goods, or that involve taking unfair advantage of the well-known character of that appellation among the public;
k) contain a protected appellation of origin for wines and spirits;
l) consist of a national or foreign geographical reference that is liable to create confusion in respect of its application to products or services;
m) reproduce or imitate, as trademarks or elements of those trademarks, without the permission of the competent authority of the State or international organization concerned, heraldic elements, such as coats of arms, flags, and emblems, and the official signs and stamps used for the purposes of government control and guarantee and the coat of arms, flags and other emblems, initials or designations of any international organization;
n) reproduce or imitate signs denoting conformity with technical standards, except where the registration thereof is applied for by the national body responsible for standards and quality requirements in Member Countries;
o) reproduce, imitate, or include the indication of a plant species protected in a Member Country or any other country, where application of the sign to goods or services relating to that species of if its use is likely to cause confusion or a mistaken association with that variety; or
p) are contrary to law, morality, public order or good manners.

Notwithstanding the provisions stipulated under items b), e), f), g) y h), a sign may be registered as a trademark where its continued use in a Member Country by the applicant or assignor has endowed it with a distinctiveness in respect of the products or services to which it is applied.

Article 136.- Those signs the use of which in commerce may constitute an impediment to the rights of third parties, may likewise not be registered as trademarks, in particular where:

a) they are identical, or similar to a trademark filed for registration or registered earlier by a third party for the same goods or services, or for goods or services in respect of which use of the trademark is likely to lead to confusion or mistaken association;

b) they are identical or similar to a protected trade name, label, or emblem that, given the circumstances, their use would result in a likelihood of confusion or mistaken association;
c) they are identical or similar to a filed for or registered advertising slogan that, given the circumstances, their use would result in a likelihood of confusion or mistaken association;
d) they are identical or so similar to a distinctive sign belonging to a third party where, the applicant being or having been a representative or distributor of the owner of the protected sign in a Member Country or elsewhere or a person expressly authorized by that right holder, their use, given the circumstances, would result in a likelihood of confusion or mistaken association;
e) consist of a sign that is capable of affecting the identity or prestige of legal entities, whether non-profit or not, or natural persons other than the applicant or identifiable by the general public as being such a different person, particularly in regard to a given name, family name, signature, title, nickname, pseudonym, image, portrait, or caricature, where no consent has been obtained from that person or, if deceased, the declared heirs of that person;
f) consist of a sign that may violate the intellectual property right or copyright of a third party, unless the consent of that party has been obtained;
g) consist of the name of indigenous, African American, or local communities, or of such denominations, words, letters, characters, or signs as are used to distinguish their products, services or methods of processing, or that constitute an expression of their culture or practice, unless the application is filed by the community itself or with its express consent; and,
h) consist of a total or partial reproduction, imitation, translation, transliteration, or transcription of a well-known sign belonging to a third party without regard to the type of product or service to which it shall be applied, the use of which would lead to a likelihood of confusion or mistaken association with that party; taking unfair advantage of the prestige of the sign; or weakening its distinctive force or its use for commercial or advertising purposes.

Article 137.- The competent national office may, when it has sufficient reason to believe that the registration was applied for in order to engage in, contribute to, or strengthen an act of unfair competition, may refuse to register that trademark.

CHAPTER II
On the Registration Procedure

Article 138.- The application for registration of a trademark shall be filed with the competent national office. It shall cover a single category of goods or services and shall meet the following requirements:

a) the petition;
b) a reproduction of the trademark where it is a denomination containing graphic elements, shape, or color, or a figurative, mixed or three-dimensional trademark with or without the use of color;
c) such powers of attorney as may be needed;
d) proof of payment of the prescribed fees;
e) the authorizations required for the cases stipulated in articles 135 and 136, where applicable; and
f) the certificate of registration in the country of origin issued by the granting authority and, if so stipulated in domestic legislation, the receipt for payment of the prescribed fee, should applicants wish to avail themselves of the right provided for in Article 6 quinquies of the Paris Convention.

Article 139.- The petition for registration of the trademark application shall be a form and shall include the following information:

a) the request for registration of a trademark;
b) the name and address of the applicant;
c) the nationality or address of the applicant and, should the applicant be a legal entity, the place of incorporation;
d) the name and address of the applicant's legal representative, if pertinent;
e) a statement of the trademark to be registered, where such trademark is denominative only, without graphics, shape or color;
f) a list of the specific goods or services for which the trademark registration application is being filed;
g) a statement of the category to which the products or services correspond; and,
h) the signature of the applicant or the applicant's legal representative.

Article 140.- The date of its receipt by the competent national office shall be considered the application filing date, provided that the application contained at least the following elements:

a) a statement that the applicant is filing for registration of a trademark;

b) data that shall permit identification of the applicant or person filing the application or enable the competent national office to communicate with that person;
c) the trademark for which registration is being applied for, or a reproduction of the trademark in the case of trademarks that are denominations with special graphic elements, shapes or colors, or of figurative, mixed or three-dimensional trademarks, whether in color or not;
d) a list of the specific goods or services in respect to which the trademark protection is being applied for; and,
e) proof of payment of the prescribed fees.

Failure of to provide any of the requirements listed in this article shall cause the competent national office to reject the application for processing and no filing date shall be assigned to it.

Article 141.- An applicant may claim as the filing date of an application for registration of a trademark the date that the trademark was used to distinguish goods or services at an officially recognized exhibition held in any country when applied for within six months following the date on which the said goods or services were first exhibited under that trademark. In that case, the application may be considered filed as from the date of the exhibition.

The acts referred to in this article shall be certified by the competent authority responsible for the exhibition, which shall state the date on which the trademark was first used in connection with the goods or services in question.

Article 142.- An applicant wishing to invoke the right provided for in Article 6 quinquies of the Paris Convention for the Protection of Industrial Property shall submit the certificate of trademark registration in the country of origin within a period of three months after the application filing date.

Article 143.- Applicants for registration of a trademark may ask to modify their applications at any time during their processing or to correct any material mistakes.

The competent national office may, at any stage of the processing, suggest that applicants make changes in their applications. The said proposal of amendment shall be processed in accordance with the provisions of article 144.

In no case may the application be amended by making important changes in the trademark or adding to the products or services initially specified.

Fees may be prescribed for the amendment application, if domestic legislation so provides.

Article 144.- The competent national office shall, within 15 days following filing, conduct an examination to determine whether the application complies with the conditions of form specified in articles 135 and 136.

Should the examination reveal that the application does not comply with the conditions of form specified in the preceding paragraph, the competent national office shall request that the applicant to remedy those defects within a period of sixty days following notification.

If the applicant fails to fulfill the requirements by the end of the stipulated term, the application shall be rejected and shall lose its position within the order of priority.

Article 145.- If the application meets the formal conditions of form laid down in this Chapter, the competent national office shall order its publication.

Article 146.- Within thirty days following such publication, any person having a legitimate interest may, one time only, file a valid objection that could result in invalidation of the trademark registration.

The competent national office may, at the request of a party and once only, grant an additional thirty-day period in which to provide valid reasons for opposing registration of the trademark.

Reckless objections may be sanctioned if provided for by domestic legislation.

No objections based on such trademarks as may have existed at the same time as that being applied for, may be lodged against the application within six months following expiry of the grace period referred to in article 153.

Article 147.- For the purposes of the previous article, it shall be understood that both the owner of an identical or similar trademark, for goods or services in respect of which use of the other trademark would be likely to lead to confusion, and the person that first applied for registration of the trademark in any Member Country, have a legitimate interest in lodging objections in the other Member Countries. In either case, such opponents shall demonstrate real interest in operating in the market of the Member Country where they are filing an objection by applying for registration of the trademark at the moment they express their opposition.

If an objection is lodged on the basis of a trademark previously registered in any Member Country under the provisions of this article, the competent national office shall have the authority to deny registry of the second trademark.

The filing of an objection based on an application for trademark registration previously filed in any Member Country under the provisions of this article shall result in the suspension of the registration of the second trademark until such time as the registration of the first has been conferred. In that event, the stipulations of the previous paragraph shall be applicable.

Article 148.- The competent national office shall, in the event of any opposition having been presented, request applicants to submit such arguments and evidence as they deem fit within thirty days following that notification.

The competent national office shall, at the request of one of the parties, grant for one time only a period of thirty additional days in which to provide valid reasons for the refutation.

Article 149.- The competent national office shall not accept for consideration such objections as:

a) are lodged without an indication being given of the essential data identifying the opponent and the application against which the objection is being filed;
b) are lodged after the deadlines have lapsed;
c) have not paid the prescribed processing fees.

Article 150.- At the expiration of the period stipulated in article 148, or if no objections have been filed, the competent national office shall proceed to conduct the examination of registrability. Should any opposition have been presented, the competent national office shall rule on those objections and on the grant or refusal of registration of the trademark and inform the parties of its decision.

Article 151.- Member Countries shall use the International Classification of Goods and Services for the Purposes of the Registration of Marks established by the Nice Agreement of June 15, 197 and its effective amendments to classify the goods and products to which the trademarks shall be applied.

The categories of the International Classification named in the previous paragraph into which those goods and services are classified shall not be used to determine whether the expressly listed products or services are similar or different.

CHAPTER III
On the Rights and Limitations conferred by the Trademark

Article 152.- Registration of a trademark shall be for a term of ten years counted from the grant date and may be renewed for successive ten-year periods.

Article 153.- The owner of a registered trademark or any party with a legitimate interest shall apply to the competent national office for its renewal within six months before expiry of its registration. Notwithstanding the foregoing stipulation, both the owner of the registered trademark and any party having a legitimate interest shall be given a grace period of six months following the date of expiration of the registration in which to apply for renewal. Such persons shall accordingly attach receipts for payment of the prescribed fees and shall, at the same time, pay any such surcharge as the domestic legislation of the Member Countries may prescribe. The registered trademark shall retain its full validity over that period.

Renewal shall not require proof of trademark use and shall be granted automatically on the same terms as the original registration. The owner of the registered trademark may, however, reduce or limit the goods or services listed in the original registration.

Article 154.- Registration of a trademark with the competent national office shall confer the exclusive right to its use.

Article 155.- The owner of a registered trademark shall have the exclusive right to prevent all third parties not having the owner's consent from engaging in the following acts:

a) using or affixing the trademark or a similar or identical distinguishing sign to products in respect of which the trademark is registered; to products connected with the services for which the trademark is registered; or to the packages, wrappings, packing, or outfittings of those products;
b) removing or changing the trademark, once it has been placed on or affixed to the products in respect of which the trademark is registered, for commercial purposes; to products connected with the services for which it is registered; or to the packages, wrappings, packing, or outfitting of those products;
c) manufacturing labels, packages, wrappings, packing, or such other materials as may reproduce or contain the trademark, and selling or storing such materials;
d) using, in the course of trade, identical or similar signs to the trademark for goods or services, where such use would result in a likelihood of confusion or mistaken association with the registration owner. In the case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed;
e) using in the course of trade identical or similar signs to a well-known trademark with respect to any goods or services, where such use, by weakening the distinctive force or the value of that trademark for commercial or advertising purposes or by taking unfair advantage of the prestige of the trademark or of its owner, could unjustly damage the registration owner's economic or commercial interests;
f) making public use of identical or similar signs to a well-known trademark, even for purposes that are non-commercial, where such use could weaken the distinctive force or value of that trademark for commercial or advertising purposes or take unfair advantage of its prestige.

Article 156.- For the purposes of the provisions stipulated under paragraphs e) and f) of the previous article, the following acts, among others, shall constitute use of a trademark by a third party in the course of trade:

a) introducing into commerce, selling, offering for sale, or distributing products or services that bear the said trademark;
b) importing, exporting, storing, or transporting products that bear the said trademark; or,
c) using the said trademark, independently of the means of communication employed and without prejudice to such standards as may be applicable to advertising, in advertising, publications, commercial documents, or written or oral communication.

Article 157.- Provided that it is done in good faith and does not constitute use as a trademark, third parties may, without the consent of the owner of the registered trademark, make use in the market of their own names, addresses, or pseudonyms, a geographical name, or any other precise indication concerning the kind, quality, amount, purpose, value, place of origin or time of production of their goods or of the rendering of their services, or other characteristics thereof, provided that such use is confined to identification or information purposes only and is not likely to create confusion over the source of the goods or services.

Trademark registration shall not confer on the owner the right to prevent a third party, where proceeding in good faith, from using the trademark to announce, even in advertising using brand comparisons, offer for sale, or advertise the existence or availability of lawfully trademarked goods or services, or from advertising the compatibility or suitability of spare parts or accessories that may be used with goods bearing the registered trademark, provided that such use is confined to the purpose of informing the public and is unlikely to lead to confusion over the corporate origin or the goods or services concerned.

Article 158.- Trademark registration shall not confer on the owner the rights to prevent third parties from engaging in trade in a product protected by registration once the owner of the registered trademark or another party with the consent of or economic ties to that owner has introduced that product into the trade of any country, in particular where any such products, packaging or packing as may have been in direct contact with the product concerned have not undergone any change, alteration, or deterioration.

For the purposes of the preceding paragraph, two persons shall be considered to have economic ties when one of the persons is able to exercise a decisive influence over the other, either directly or indirectly, with respect to use of the trademark right or when a third party is able to exert that influence over both persons.

Article 159.- Where registrations of an identical or similar mark exist in the Subregion in the name of different owners for the identification of the same goods or services, the marketing of the goods or services identified with that mark in the territory of the Member Country concerned shall be prohibited, except where the owners of the said marks enter into agreements allowing such marketing.

In the event of such agreements having been entered into, the parties shall take the necessary precautions to avoid misleading the public as to the origin of the goods or services concerned, which shall include matters relating to the identification of the origin of the goods or services in question in appropriate and prominent characters for the proper information of the consuming public. The said agreements shall be registered with the competent national offices and shall conform to the standards governing business practices and the promotion of competition.

In any event, the importation of a product or service that is in the situation described in the first paragraph of this Article shall not be prohibited where the mark is not being used on the territory of the importing country, as provided in the first paragraph of Article 166, except where the owner of the said mark satisfies the competent national office that the non-use of the mark is justified by legitimate factors.

Article 160.- Where the trademark consists of a geographical name, the product may not be marketed without bearing visible and clearly legible identification of its place of manufacture.

CHAPTER IV
On the Licensing and Assignment of Trademarks

Article 161.- A trademark that is registered or for which registration has been filed shall may be assigned or to transfered by succession that trademark, with or without the business to which it belongs.

Any assignment or transfer of a trademark registration shall be filed with the competent national office. Failure to register shall render the assignment or transfer invalid with respect to third parties.

An assignment or transfer, in order to be registered, shall be in writing.

Any interested party may file for registration of an assignment or transfer. The competent national office may deny that registration, if the transfer is likely to cause confusion.

Article 162.- The owner of a trademark that is registered or being filed for may license one or more parties to use the trademark in question.

Any license that is granted for use of a trademark shall be registered with the competent national office. Failure to register shall render the license invalid with respect to third parties.

The license, in order to be registered, shall be made in writing.

Any interested party may request the registration of a license.

Article 163.- The competent national authority shall not register any trademark licensing agreements or assignments or transfers that do not conform to the provisions of the Common Regime for the Treatment of Foreign Capital and for Trademarks, Patents, Licenses, and Royalties, or that do not conform to Andean Community or domestic untitrust.

Article 164.- The owner of the registered trademark shall report to the competent national office, during the license's period of effectiveness, any change in the name or address of the registered trademark owner. Otherwise any notification that is made using the data entered in the registration.

CHAPTER V
On the Cancellation of Registration

Article 165.- The competent national office shall, at the request of an interested party, cancel a trademark registration after an uninterrupted period of non-use in any Member Country, without valid reasons, by the owner, a licensee, or another person authorized by the owner, of at least three years immediately before the start of the cancellation proceeding. Cancellation of a registration for non-use of trademark rights may also be requested as a defense in an opposition proceeding lodged on the basis of the unused trademark.

Without prejudice to the stipulation of the previous paragraph, no cancellation proceeding shall be initinted until three years after the date of notification of the final resolution within the administrative registration procedures relating to the.....

Where non-use of a trademark affects only one or several of the goods or services in respect of which it was registered, an order shall be given to shorten or limit the list of products or services originally included in the

trademark registration in order to remove those goods and services in respect of which the trademark has not been used; the identity or similarity of the goods or services shall be taken into consideration for this purpose.

Registration may not be cancelled where the owner of the trademark is able to show that non-use is due to force majeure or an Act of God, among other things.

Article 166.- A trademark shall be considered in use where the goods or services distinguished by it have been placed in circulation or are available on the market under that trademark, in the form and amounts that are normal, due account being taken of the nature of the goods or services and the methods used for their marketing.

A trademark shall also be considered in use if it distinguishes only goods that are intended for exportation from any of the Member Countries, as stipulated in the previent paragraph. .

Use of a trademark in a form different from that in which it was registered only with respect to details or features that do not alter its distinctive character shall not constitute grounds for cancellation of registration for non-use, or lessen the protection afforded to the trademark.

Article 167.- The burden of proof of trademark use shall rest with the owner of the registration.

Commercial invoices, accounting documents, or auditing certificates, that demonstrate the regular nature and amount of trade that exists in the goods identified by the trademark may be employed to prove trademark use, among others.

Article 168.- The person who obtains a favorable ruling shall have the preferential right to registration. This right may invoked at the filing time of the request for cancellation or within three months following the effective date of the decision that ended the administrative procedure for trademark cancellation.

Article 169.- Where the owner of the trademark has caused or allowed that trademark to become a common or generic sign to identify or denote one or several or the goods or services for which it was registered, the competent national office shall order, ex officio or at the request of a party, the cancellation of the trademark or the limitation of its scope.

A trademark shall be considered to have become a common or generic sign if, in commercial circles and for the public, it has lost its distinctive character as an indication of the corporate source of the product or service to which it is applied. In order for this to occur, the following elements shall exist in relation to the trademark:

a) the need of competitors, given the absence of any other appropriate name or sign for designating or identifying in their trade the good or service in question, to use the sign to carry out their business activities;
b) widespread use of the trademark by the general public and among commercial circles as the common or generic indication of the good or service in question; and
c) ignorance or limited knowledge by the public that the trademark denotes a specific corporate origin.

Article 170.- On receipt of petitions to cancel registrations, the competent national office shall request the owners of the trademarks in question to assert their arguments and submit the proof they deem fit within sixty working days counted from the date of notification.

At the expiration of the period stipulated in this article, the competent national office shall proceed to decide whether or not to cancel the trademark registration and shall inform the parties of its decision through a resolution.

CHAPTER VI
On the Renunciation of Registration

Article 171.- Owners of a registration may at any time renounce their rights to the registration.

Where renunciation is partial, the cancellation of the registration shall relate only to those goods or services that the owner has renounced.

Renunciation shall not be permitted where there are encumbrances or real guaranty rights that are registered with the competent national office, unless the owners of those rights have given their express consent to such renunciation.

Renunciation of a trademark shall become effective only when registration of the renunciation with the competent national office has taken place.

CHAPTER VII
On the Invalidation of Registration

Article 172.- The competent national authority shall, either ex officio or at the request of a party, and at any time, declare the registration of a trademark absolutely null and void where it has been granted in contravention of the provisions of articles 134, paragraph one, and 135.

The competent national authority shall,, either ex officio or at the request of a party, declare the relative invalidation of a trademark registration where granted in contravention of the provisions of article 136 or obtained in bad faith. This action will lapse five years following the grant date of the contested registration.

The above-cited actions shall in no way affect such actions as may be brought for damages under domestic law.

A registered trademark may not be declared null and void on grounds that have ceased to be applicable at the time of the proceeding for invalidation.

When grounds for invalidation are applicable only to one or some of the goods or services for which the trademark was registered, invalidation shall be pronounced only in respect of those goods or services, and they shall be removed from the trademark registration.

Article 173.- The provisions of article 78 shall be applicable to this Chapter.

CHAPTER VIII
On the Lapsing of Registration

Article 174.- Registration of a trademark shall lapse by operation of law where the owner or the person having a legitimate interest does not request renewal within the legal time limit, including the period of grace, as provided for in this Decision.

Failure to pay fees under the terms stipulated by the domestic legislation of the Member Country shall likewise be grounds for lapse.

TILTE VII
ON ADVERTISING SLOGANS

Article 175.- Member Countries may register advertising slogans as trademarks in conformity with the respective domestic legislation.

An advertising slogan is understood to mean the word, phrase, or caption used to complement a trademark.

Article 176.- The application for registration of an advertising slogan shall specify the filed for or registered trademark with which it shall be used.

Article 177.- Advertising slogans that contain references to similar products or trademarks to expressions that may be damaging to such products or trademarks may not be registered.

Article 178.- An advertising slogan shall be assigned or transferred together with its associated trademark and its validity shall be subject to that of the trademark.

Article 179.- The relevant provisions of the Title on Trademarks of this Decision shall be applicable to this Title

TITLE VIII
ON COLLECTIVE TRADEMARKS

Article 180.- A collective trademark shall be understood to be any sign that serves to distinguish the origin or any other characteristic common to goods or services from different businesses that use the sign under the owner's control.

Article 181.- Legally established associations of producers, manufacturers, service providers, organizations, or groups of persons may apply for the registration of a collective trademark in order to distinguish in the market the goods or services of their members .

Article 182.- An application for registration shall specify that it is for a collective trademark, and shall be accompanied by:

a) a copy of the articles of association of the organization, association, or group of persons applying for registration of the collective trademark;
b) the membership list; and,
c) a statement of the conditions on and form in which the collective trademark shall be used in connection with the goods or services.

Once registration of the collective trademark has been obtained/granted, the association, organization, or group of persons shall inform the competent national office of any changes that may have been made in any of the documents referred to in this article.

Article 183.- The collective trademark may be assigned, transferred, or licensed in accordance with the internal bylaws of the association, organization, or group of persons.
These assignments, transfers, and licenses, in order to take effect in regard to third parties, shall be registered.

Article 184.- The relevant provisions of the Title on Trademarks of this Decision shall be applicable to this Title.

TITLE IX
ON CERTIFICATION MARKS

Article 185.- A certification mark shall be understood to be any sign that is intended to be applied to goods or services, the quality or other characteristics of which have been certified by the owner of the mark.

Article 186.- A certification mark may be owned by a public or private business or institution; or a state, regional, or international organization.

Article 187.- An application for registration of a certification mark shall be accompanied by the regulations for use of the certification mark, stating which goods or services may be subject to certification by the owner of the mark, defining the characteristics guaranteed by the presence of the mark, and describing the control to which those characteristics shall be subjected before and after use of the certification mark.

The regulations for use of the certification mark shall be registered together with the mark.

The competent national office shall be informed of any change in the rules for use of the certification mark, which shall take effect in regard to third parties as of the date they are entered in the appropriate registry.

Article 188.- The owner of a certification mark may authorize its use by any person whose good or service complies with the conditions prescribed in the regulations for use of that mark.

The certification mark may not be used in connection with the goods or services produced, loaned, or marketed by the owner of that certification mark.

Article 189.- The relevant provisions of the Title on Trademarks of this Decision shall be applicable to this Title.

TITLE X
ON TRADE NAMES

Article 190.- A trade name is understood to mean any sign that identifies an economic activity, a business, or a commercial establishment.

A business or establishment may have more than one trade name, including its firm name, corporate name, company name, or any other name that may be entered in the corporation registries or registries of commercial concerns.

Trade names exist independently of the company or firm names of juridical persons and it is possible for the two of them to exist at the same time.

Article 191.- Exclusive right to a trade name is acquired through use by a legal person for the first time in commercial activities and ends when the use of the name or activities of the business or establishment using that trade name cease to exist.

Article 192.- The owner of a trade name may prevent the use in commercial activity by third parties of an identical or similar distinctive sign, where such use would result in a likelihood of confusion or the risk of association of that sign with the owner or the products or services belonging to that owner; in the case of well-known trade names, where such use could produce unjust economic or commercial injury to the owner or involve taking unfair advantage of the prestige of the owner's name or business.

The provisions contained in articles 155, 156, 157, and 158 shall be applicable to trade names, as relevant.

Article 193.- The owner of a trade name may, in accordance with the domestic legislation of each Member Country, register or deposit the name with the competent national office. This registration or deposit shall be in the nature of a declaration only. Right to its exclusive use shall be acquired only as specified in article 191.

Article 194.- Signs that are included in the following cases are not eligible for registration as a trade name:

a) when they consist totally or in part of a sign that is contrary to morality or public order;
b) when their use is liable to create confusion in commercial circles or in the public as to the identity, nature, activities, line of business, or any other aspect of the company or establishment that is designated by that name;
c) when their use is liable to cause confusion in commercial circles or in the public as to the corporate source, origin, or other characteristics of the goods or services produced or marketed by the company; or,
d) where a prior application for or registration of the trade name already exists.

Article 195.- In order to register the trade name, the competent national office shall first make an examination to determine whether it contravenes the stipulations of the foregoing article. Member Countries may demand proof of its use as specified in their domestic legislation
The classification of goods and services used for the trademarks may be applicable to the registration of a trade name.

Article 196.- Registration of a trade name shall be for a term of ten years counted from the date of registration or deposit and may be renewed for successive ten-year periods.

Article 197.- The owner of a registered trade name may renounce the rights to that registration. Renunciation of the registration of a trade name shall come into effect only when that renunciation has been registered with the competent national office.

Article 198.- The owner of a trade name shall apply to the competent national office for its renewal within six months before expiry of its registration. Notwithstanding the foregoing stipulation, the owner of the trade name shall be allowed a grace period of six months following the date of expiration of the registration in which to apply for its renewal, at that time attaching receipts for payment of the fees prescribed in the domestic legislation of the Member Countries and paying any such surcharge as may be prescribed for. The registered trade name shall retain its full validity over that period.

For purposes of the renewal of a trade name, the competent national offices may demand proof of its use as specified in domestic legislation. In any case, the renewal shall be carried out on the same terms as the original registration.

Article 199.- The assignment of a registered or deposited trade name shall be registered with the competent national office in accordance with the procedure applicable to the assignment of trademarks, as relevant, for which the same fee shall be payable. Without prejudice to the foregoing, a trade name may only be assigned together with the business or establishment with which it is being used.

A trade name may be licensed. That license may be registered with the competent national office when so stipulated by domestic legislations.

TITLE XI
ON LABELS OR EMBLEMS

Article 200.- The protection and deposit of labels or emblems shall be governed by the provisions in respect of trade names, in accordance with the domestic legislation of each Member Country.

TITLE XII
ON GEOGRAPHICAL INDICATIONS

CHAPTER I
On Appellations of Origin

Article 201.- An appellation of origin shall be understood to be a geographical indication consisting of the name of a particular country, region, or locality, or of a name which, without being that of a particular country, region, or locality, refers to a specific geographical area, which name is used to identify a product originating therein, the qualities, reputation, or characteristics of which are exclusively or essentially attributable to the geographical environment in which it is produced, including both natural and human factors.

Article 202.- Those appellations of origin may not be declared such that:

a) do not conform to the definition contained in article 201;
b) are common or generic terms that distinguish the product concerned, that is, terms considered as such both by persons with knowledge of the area concerned and by the general public;
c) are contrary to good manners or the public order; or,
d) are liable to mislead the public as to the geographical source, nature, means of manufacture, or quality, reputation, or other characteristics of the products in question.

Article 203.- The declaration of protection of an appellation of origin shall be made ex officio or at the request of persons who are able to prove a legitimate interest, such being natural persons or legal entities directly engaged in the extraction, production, or processing of the product or products to be covered by the geographical indication, as well as associations of producers. Where the appellations of origin refer to their own jurisdictions, state, departmental, provincial, or municipal authorities shall likewise be considered interested parties.

Article 204.- The application for a declaration of protection of an appellation of origin shall be filed in writing with the competent national office and shall specify the following:

a) name, domicile, residence, and nationality of the applicant or applicants and proof of their legitimate interest;
b) the appellation of origin in respect of which the declaration is filed;
c) the demarcated geographical area within which the production, extraction, or processing of the product to be identified by the appellation of origin takes place;
d) the products that are designated by the appellation of origin; and,
e) a summary of the essential qualities, reputation, or other characteristics of the products that are designated by the appellation of origin.

Article 205.- Where the application has been accepted for consideration, the competent national office shall, within the following thirty days, ascertain whether it complies with the requirements stipulated in this Title and those established in the domestic legislation of the Member Countries, whereupon it shall observe the procedure for examining whether the trademark meets the conditions of form, insofar as pertinent.

Article 206.- The validity of the declaration of protection of an appellation of origin shall be subject to the continuing existence of the conditions on which it was based, as determined by the competent national

office, which may declare the validity terminated if the said conditions no longer obtain. Nevertheless, interested parties may reapply for renewal of the said validity where they consider that the conditions on which protection was based have been restored, without prejudice to administrative appeals provided for in the domestic legislation of each Member Country.

The declaration of protection of an appellation of origin may be amended at any time where there is a change in any one of the elements to which article 204 refers, such amendment to follow the stipulated procedure for the declaration of protection, insofar as it is applicable.

Article 207.- Authorization to use a protected appellation of origin may be requested for by those persons who:

a) are directly engaged in the extraction, production, or processing of the products identified by the appellation of origin;
b) perform the said activity within the demarcated geographical area specified in the declaration of protection; and,
c) comply with other requirements imposed by the competent national offices.

Article 208.- Competent national offices may grant authorizations to use the said geographical indications.

Such authorization may also be accorded by the public or private institutions that represent those benefited by the appellations of origin, if permitted by domestic provisions.

Article 209.- Where the competent national office is responsible for authorization to use an appellation of origin, it shall be granted or denied within a period of fifteen days following the filing date of the application.

Article 210.- Authorization to use a protected appellation of origin shall be for a term of ten years and may be renewed for successive ten-year periods, in accordance with the procedure stipulated in this Decision for the renewal of trademarks.

Article 211.- Authorization to use a protected appellation of origin shall lapse if its renewal is not applied for within the period stipulated in this Decision for the renewal of trademarks.

Failure to pay fees shall likewise be grounds for lapse, under the conditions specified in the domestic legislation of each Member Country.

Article 212.- The use of appellations of origin with respect to natural, agricultural, handicraft, or industrial products from the Member Countries shall be reserved exclusively for producers, manufacturers, and craftsmen with production or manufacturing establishments in the locality or region within the Member Country identified or evoked by that appellation.

Only producers, manufacturers, or craftsmen authorized to use a registered appellation of origin may employ together with that appellation the term "APPELLATION OF ORIGIN".

The provisions stipulated in articles 155, 156, 157, and 158 shall be applied in respect of protected appellations of origin, as relevant.

Article 213.- Public or private institutions representing parties benefited by appellations of origin or such parties as are so designated, shall possess the mechanisms allowing for effective control to be exercised over the use of protected appellations of origin.

Article 214.- The competent national office with its announcement shall start the period of protection of an appellation of origin.

Use by unauthorized persons of appellations of origin, including cases where such use is accompanied by indications of gender, type, imitation and other similar indications, in such manner as is likely to cause confusion among consumers, shall be considered an infringement of that intellectual property right and as such, sanctionable by punishment.

Article 215.- Member Countries shall prevent use of a geographical indication identifying wines or spirits for goods of this kind not originating in the place indicated by the appellation of origin in question, even where the true origin of the goods is indicated or the apellation of origin is used in translation or accompanied by expressions such as "kind", "type", "style", "imitation," or the like.

Member Countries may not prevent continued and similar use of a particular apellation of origin of another country identifying wines and spirits in connection with goods or services by any of their nationals who have used that geographical indication in a continuous manner with regard to the same or related goods or services within the territory of the respective Member Country for at least 10 years preceding April 15, 1994 or, in good faith, preceding that date.

Article 216.- The competent national authority shall, either ex officio or at the petition of one of the parties, declare the authorization to use a protected appellation of origin null and void if granted in violation of this Decision. The provisions stipulated in this Decision in respect of trademark invalidation shall be applicable in this case, as relevant.

Article 217.- The competent national office shall, either ex officio or at the request of one of the parties, where use not in keeping with the provisions of the respective declaration of protection is proven, cancel the authorization for use of the appellation of origin. The relevant provisions stipulated in this Decision with regard to trademark cancellation shall be applicable in this case.

Article 218.- Competent national offices shall, where the petition is made by producers, extractors, manufacturers, or craftsmen with a legitimate interest in the matter or the respective public authorities, recognize appellations of origin protected in another Member Country.

Appellations of origin, in order to be eligible for such protection, must have been declared as such in their countries of origin.

Article 219.- Competent national offices shall recognize the protection accorded by third countries to appellations of origin or geographic indications, provided that an agreement to which the Member Country in question is a part so specifies. To be eligible for such protection, those appellations of origin must have been declared as protected in their countries of origin.

Article 220.- Appellations of origin protected in accordance with the stipulations of this Decision shall not, so long as that protection obtains, be considered common or generic in distinguishing the product they indicate.

CHAPTER II
On indications of origin

Article 221.- An indication of origin shall be understood to be a name, expression, image, or sign that indicates or evokes a particular country, region, locality, or place.

Article 222.- An indication of origin may not be used in the course of trade for a good or service where that indication is false or misleading or where its use is likely to cause confusion in the public as to the origin, source, quality, or any other characteristic of the good or service in question.

For purposes of the stipulation of the previous paragraph, its use in advertising or in any commercial documents concerning the sale, exhibition, or offering of goods and services also constitutes use of a geographical indication.

Article 223.- Persons may state their names and domiciles on the goods they market, even if those products come from another country, provided that the country or place where those goods are manufactured or produced is specifically and clearly stated also, together with any other indications that may be needed to avoid mistaking their true origin.

TITLE XIII
ON WELL-KNOWN DISTINCTIVE SIGNS

Article 224.- A well-known distinctive sign is understood to mean a sign that is recognized as such in any Member Country by the pertinent sector, independently of the way or means by which it was made known.

Article 225.- A well-known distinctive sign shall be protected from use or registration that is not authorized pursuant to the stipulations of this Title, without prejudice to such other provisions of this Decision as may be applicable and to the provisions of the Member Country in respect of protection against unfair competition.

Article 226.- Use of all or a part of a well-known distinctive sign or the reproduction, imitation, translation, or transliteration thereof, that may create confusion in respect of identical or similar businesses, activities, products or services to those to which it is applied, shall constitute unauthorized use of that distinctive sign.

Also constituting unauthorized use of a well-known distinctive sign is the use of all or of a essential part of that sign, or the reproduction, imitation, translation, or transliteration thereof, even if in respect of businesses, activities, goods, or services other than those to which that well-known distinctive sign is applied, or its use for non-commercial purposes, where such use could be liable to produce any of the following effects:

a) the risk of confusion or of association with the owner of the sign, or with the businesses, activities, goods, or services belonging to that owner;
b) unjust economic or commercial injury to the owner of the sign by reason of the weakening of the distinctive force or commercial or advertising value of that sign; or,
c) unfair exploitation of the sign's prestige or fame.
Use of a distinctive sign may be verified by any means of communication, including electronic media.

Article 227.- The provisions contained in articles 136 h) and 155 e) and f) shall be applicable to this Title.

Article 228.- In order to determine whether a distinctive sign is well-known, due account shall be taken of the following criteria among a thing :

a) the extent to which it is known in the relevant sector of the public in any Member Country;
b) the age of the distinctive sign and the size of the geographical area where it is used in and outside any Member Country;
c) the age and the size of the geographical area where the distinctive sign is promoted, in or outside any Member Country, including its advertising and presentation at fairs, exhibitions, or other events in connection with the goods or services, the establishment, or the activity to which it is applied;
d) the value of all investments made in promoting the distinctive sign or the establishment, activity, goods or services to which it is applied;
e) figures for the sales and income of the owner, both at the international level and in the Member Country where protection is being sought, in respect of the distinctive sign whose well-known character is alleged;
f) the extent of the inherent or acquired distinctiveness of the sign;
g) the book value of the sign as a corporate asset;
h) the volume of orders from persons interested in obtaining a franchise or license to the sign in a specific territory; or,
i) the existence of significant manufacturing, purchasing, or storage activities by the owner of the sign in the Member Country where protection is being sought;
j) the international trade-related aspects; or,
k) the existence or age of any registration or application for registration of the distinctive sign in the Member Country concerned or in any other country.

Article 229.- The well-known nature of a sign shall not be denied solely because:

a) it is not registered or in the process of being registered in the Member Country concerned or in any other country;
b) it has not been nor is it being used to distinguish goods or services or to identify activities or businesses in the Member Country concerned; or,
c) it is not well-known abroad.

Article 230.- The following, among others, shall be considered pertinent sectors of reference for purposes of determining whether a sign is well-known:

a) the real or potential consumers of the type of goods and services to which the sign shall be applies;
b) the persons involved in the channels of distribution or marketing of the kinds of goods or services to which the sign shall be applied; or,
c) the commercial circles operating in lines of business connected with the kind of establishment, activity, goods, or services to which the sign applies.

It shall be sufficient, for the purpose of recognizing the well-known character of a sign, for it to be known within any of the sectors referred in the previous paragraphs.

Article 231.- The owner of a well-known distinctive sign may take action to prevent its use by third parties and may bring such action and take such measures as may be appropriate with the competent national authority. That owner may also prevent a third party from engaging in such acts in respect of the sign as are stipulated in article 155, the limitations established in articles 157 and 158 being applicable.

Article 232.- The right to action against unauthorized use of a well-known distinctive sign shall lapse five years counted from the date on which the owner was informed of that use, except where such use was started in bad faith, in which case that right to action shall not lapse. Such action shall not affect any action for damages that may be brought pursuant to domestic law.

Article 233.- The competent national authority shall, at the request of the owner or lawful right holder in respect of a well-known distinctive sign, where the said sign has been unlawfully registered by an unauthorized third party in a Member Country as part of a dominion name or electronic mailing address, order the cancellation or amendment of that registration of dominion or electronic mailing address, provided that use of that name or address is likely to have one of the effects cited in the first and second paragraphs of article 226.

Article 234.- A competent national authority shall, in making a decision on an action for unauthorized use of a well-known distinctive sign, bear in mind the good or bath faith displayed by the parties in the adoption and use of that sign.

Article 235.- Without prejudice to any action that may be taken in regard to the grounds for cancellation stipulated in articles 165 and 169, if permitted by domestic legislation, a competent national office shall cancel the registration of a trademark at the petition of the legitimate owner of that trademark where it is identical or similar to one that was well-known, according to the legislation in force, at the time registration was applied for.

Article 236.- The pertinent provisions contained in this Decision shall be applicable to this Part.

TITLE XIV
ON THE RIGHT OF ACTION FOR REVINDICATION

Article 237.- Where patents or registration of industrial designs have been applied for or obtained by persons with no right to those patents or registrations, or in detriment of other parties also possessing that right, the parties affected may claim those rights from the competent national authority and request the transfer to them of the applications being processed or the right grants, or their recognition as coapplicants or coowners of those rights.

Where trademark registrations have been filed for or obtained to the detriment of other parties with the same rights, the parties affected may make claims to such rights with the competent national authority by requesting their recognition as coapplicants or coowners of the rights in question.

Should the domestic legislation of the Member Country so permit, compensation for damages may be requested in the same claim.

The right to bring this action shall lapse four years after the protected of the subject matter or two years as from the date of first exploitation or use in the country by the person having obtained that right of the subject matter of the protection, whichever period expires first, except where the right was obtained in bad faith, in which case the right to bring that claim shall not lapse.

TITLE XV
ON ACTIONS FOR INFRINGEMENT OF RIGHTS

CHAPTER I
On the Rights of the Owner

Article 238.- Owners of a right protected by virtue of this Decision may bring action with the competent national authority against any persons infringing upon their right and also against any persons performing acts that are extremely likely to result in the infringement of that right.

The competent national authority may, ex officio and if permitted by the domestic law of the Member Country concerned, initiate the proceedings for infringement stipulated in that legislation.

In case of the coownership of a right, any one of the coowners may bring action for infringement without need for consent from the other parties, unless there is an agreement to the contrary among the coowners.

Article 239.- The owner of a patent shall have the right to take legal action for damages resulting from unauthorized use of the invention or utility model between the period when it became public knowledge and the respective application was opened to consultation and the patent grant date. Compensation shall be lawful only in respect of the subject matter covered by the patent grant, and shall be computed in accordance with the patent's effective exploitation by the defendant over the period in question.

Article 240.- In cases where infringement of a patent on a process for obtaining a product is claimed, defendants shall be liable to prove a difference between the procedure they use to obtain the product and the procedure protected by the patent whose infringement is claimed. Any identical product produced without the consent of the patent owner shall be presumed, on these regards and unless otherwise proven, to have been obtained through the patented process, if:

a) the product obtained by means of the patented process is a new product; or
b) there is a strong likelihood that the identical product was manufactured through the patented process and the patent owner is unable, despite reasonable efforts, to determine the process effectively used.

Consideration shall be given, in the presentation of evidence to the contrary, to the legitimate interests of the defendant insofar as the protection of their business secrets is concerned.

Article 241.- The plaintiff or defendant may request the competent national authority to order one or more of the following measures, among others:

a) cessation of all acts that constitute the infringement;
b) compensation for damages;
c) withdrawal from commercial channels of all products resulting from the infringement, including packaging, wrappings, labels, printed materials or advertising, together with the materials and implements, the predominant use of which has been the commission of the infringement;
d) prohibition against the importation or exportation of the products, or materials or implements referred to in the previous item;
e) adjudication of the ownership of the products or materials or implements referred to in item c), in which case the value of such goods shall be charged to the amount of compensation due for damages;
f) adoption of the necessary measures to avoid continuation or repetition of the infringement, including destruction of the products or materials or implements referred to in item c) or the temporary or definitive closure of the business belonging to the defendant or the accused; or,
g) publication of the guilty verdict and notification of interested parties at the infringer's expense.

In the case of counterfeit trademark goods, the elimination or removal of that trademark shall be accompanied by actions to prevent the introduction of these products into commerce. Furthermore, such goods shall not be allowed to be re-exported in an unaltered state or to be subjected to a different customs procedure.

Cases duly qualified by the competent national authority or those expressly authorized by the owner of the trademark shall be excepted.

Article 242.- Member Countries may, unless out of proportion to the seriousness of the infringement, instruct judicial authorities to order infringers to tell right holders the names of third parties having taken part in the production and distribution of the infringing goods or services, and about the channels used for distribution of such goods.

Article 243.- The following criteria shall be used, among others, to calculate the amount of compensation to be paid for damages:

a) the consequential damage and lost profits suffered by the right holder as a result of the infringement;
b) the amount of profit obtained by the infringer as a result of the acts of infringement; or,
c) based on the commercial value of the infringed right and such contractual licenses as may have already been granted, the price the infringer would have paid for a contractual license.

Article 244.- The right to action for infringement shall lapse two years counted as of the date the owner learned about the infraction or, in any case, five years after the infringement was committed for the last time.

CHAPTER II
On Provisional Measures

Article 245.- Any party initiating or who shall initiate an action for infringement may request the competent national authority to order immediate provisional measures for the purpose of preventing an infringement from occurring, avoiding its consequences, obtaining or preserving evidence, or ensuring the effectiveness of the action or compensation for damages.

Provisional measures may be requested before starting the action, together with it, or after it has been initiated.

Article 246.- The following provisional measures may be ordered, among others:

a) immediate cessation of all acts constituting the alleged infringement;
b withdrawal from commercial channels of all products resulting from the alleged infringement, including packaging, wrappings, labels, printed material or advertising, or other materials, together with the materials and implements the predominant use of which has been the commission of the infringement;
c) suspension of the importation or exportation of the goods or materials or implements referred to under the previous paragraph;
d) establishment by the alleged infringer of an adequate guarantee; and,
e) temporary closure of the business belonging to the defendant or accused, if necessary, to avoid continuation or repetition of the alleged infringement.

The competent national authority may, if permitted by the domestic law of the Member Country concerned, order the application of provisional measures ex officio.

Article 247.- A provisional measure shall be ordered only where the persons requesting it accredit their lawful right to act and the existence of the infringed right, and provide evidence allowing for a reasonable presumption of infringement or that infringement is imminent. The competent national authority may require persons requesting the measure to post a hand or sufficient equivalent assurance before ordering such a measure.

The applicant for a provisional measure in respect of particular goods shall supply the necessary information and a sufficiently detailed and precise description so that the allegedly infringing goods can be identified
;
Article 248.- Where a provisional measure has been adopted inaudita altera parte, the party affected shall be given notice without delay after the execution of the measures. The defendant may request the competent national authority to conduct a review of the executed measure.

Unless stipulated otherwise, any provisional measure executed inaudita altera parte shall cease to have effect by operation of law if infringement proceedings are not initiated within ten days following the execution of the measure.

The competent national authority may modify, revoke, or confirm the provisional measure.

Article 249.- Provisional measures shall be applied to the goods resulting from the alleged infringement and to the materials or implements, the predominant use of which has been the commission of the infringement.

CHAPTER III
On Border Measures

Article 250.- The owner of a registered trademark who has valid grounds for suspecting that the importation or exportation of counterfeit trademark goods will take place, may request the competent national authority to suspend this customs operation. The conditions and hand stipulated in the domestic legislation of the Member Country concerned shall be applicable to this request and to such an order as that authority may issue.

The party requesting measures to be taken at the border shall be required to supply the necessary information and a sufficiently detailed and precise description of the goods subject to the alleged infringement so they can be identified.

The competent national authority may, if permitted by the domestic laws of the Member Country, order the application of measures at the border ex officio.

Article 251.- The competent national authority shall give trademark owners the opportunity to participate in the inspection of the detained goods in order to substantiate their claims. The importer or exporter of those goods shall be entitled to exercise the same right.

The competent national authority shall make all necessary arrangements for confidential information to be protected during the inspection procedure.

Article 252.- Upon fulfillment of the applicable conditions and hand provisions, the competent national authority shall order deny the suspension of the customs operation and shall inform the applicant accordingly.

In the event that the authority orders the operation to be suspended, the notification of the applicant shall include the name and address of the consigner, importer, exporter, and consignee of the goods concerned, and the amount of goods to be detained. The importer or exporter of those goods shall be likewise notified of the suspension.

Article 253.- If, within ten working days after the applicant has been served notice of the suspension of the customs operation, the plaintiff fails to initiate infringement proceedings or the competent national authority has not taken measures to prolong the suspension, the measure shall be revoked and the detained goods shall be released.

Article 254.- If infringement proceedings have been initiated, the defendant may appeal to the competent national authority, which shall decide whether to modify, revoke, or confirm the suspension.

Article 255.- Once the existence of an infringement has been determined, such counterfeit trademark goods as the competent national authority may have seized may not be re-exported in an unaltered state or subjected to a different customs procedure, except in cases duly qualified by the competent national authority or expressly authorized by the right holder.

Without prejudice to other rights of action available to the right holder and subject to the right of the defendant to seek review by a judicial authority, the competent national authorities shall have the authority to order the destruction or seizure of infringing goods.

Article 256.- Small quantities of goods of a non-commercial nature contained in traveler's luggage or sent in small consignments shall be excluded from the application of the provisions of this chapter.

CHAPTER IV
On Criminal Procedures

Article 257.- Member Countries shall provide for criminal procedures and penalties to be applied in cases of trademark counterfeiting.

TITLE XVI
ON INTELLECTUAL PROPERTY-LINKED TRADE PRACTICES

CHAPTER I
On Acts of Unfair Trade Practices

Article 258.- Any act carried out in respect of intellectual property in the course of trade that is contrary to honest commercial practices shall be considered unfair.

Article 259.- The following, among others, constitute intellectual property-linked unfair trade practices:

a) any act which, by any means whatsoever, is capable of causing confusion with respect to the business, goods, or industrial activity of a competitor;
b) false affirmations made in the course of trade that are capable of discrediting a competitor's business, goods, or industrial or commercial activity; or,
c) indications or affirmations whose use in the course of trade may mislead the public with regard to the nature, method of manufacture, characteristics, usefulness, or quantity of the goods in question.

CHAPTER II
On Industrial Secrets

Article 260.- An industrial secret shall be considered to be any undisclosed information within the lawful control of an individual person or legal entity that may be used for any productive, industrial, or commercial activity and that is capable of being transmitted to a third party, so long as that information:

a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
b) has commercial value because it is secret; and
c) has been the subject of reasonable steps by the person lawfully in control of the information, to keep it secret.

The information constituting an industrial secret may be related to the nature, characteristics, or purpose of the products, production methods or processes, or the means or forms of distribution or marketing of goods or rendering of services.

Article 261.- For purposes of this Decision, information whose disclosure is the result of a legal provision or court order shall not be considered an industrial secret.

Information provided to any authority or disclosed by legal provision by the person in lawful possession of it shall not be considered public property if that person supplies the information for the purpose of obtaining licenses, permits, authorizations, registrations, or any other legal acts.

Article 262.- Persons shall have the possibility of preventing an industrial secret lawfully within their control from being disclosed to, acquired by, or used by third parties in a manner contrary to fair trade practices. Performance of any of the following acts in respect of an industrial secret shall be considered unfair competition:

a) using, without the authorization of the person lawfully in control of that information, an industrial secret to which the third party had access under a confidentiality obligation resulting from a contractual or labor trade practice;
b) communicating or disclosing, without the consent of the personal lawfully in control of that information, the industrial secret referred in subsection a) with the intent of obtaining advantages for oneself or another party or of causing injury to the person in control of that information;
c) acquiring an industrial secret by means that are unlawful or contrary to fair practice practices;
d) using, communicating, or disclosing an industrial secret acquired in the way described in subsection c);
e) using an industrial secret obtained from another person, while knowing, or negligently failing to know, that the party who communicated the secret had acquired it by use of the means cited under subsection c), or did not have consent to communicate it from the person lawfully in control of that information;
f) communicating or disclosing an industrial secret obtained in the way described under subsection e), for the benefit of oneself or a third party or to injure the person lawfully in control of that industrial secret.

An industrial secret shall be considered to have been acquired by means contrary to fair trade practices where such acquisition is the result of industrial espionage, breach of contract or other obligations, breach of trust, breach of a duty of secrecy, or inducement to breach.

Article 263.- Protection of an industrial secret shall last so long as the conditions set out in article 260 exist

Article 264.- Any person lawfully in control of a trade secret may transfer it to a third party or authorize its use by a third party. That authorized user shall be under the obligation not to disclose the industrial secret by any means, unless otherwise agreed with the person having transferred or authorized use of that secret.

Agreements for the transfer of technological know-how, technical assistance, or the provision of basic or detailed engineering may include confidentiality clauses to protect the trade secrets contained therein, provided that such clauses are not contrary to antitrust provisions on free competition.

Article 265.- Persons with access to an industrial secret by reason of their work, employment, job, professional performance, or business relationship and warned of the confidentiality thereof, shall refrain from making use of it or disclosing it without just cause and without the consent of the owner or authorized user of that secret.

Article 266.- Member Countries, when requiring, as a condition for approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Member Countries shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

Member Countries may take steps to guarantee the protection provided for under this article.

CHAPTER III
On the Rights of Action for Unfair Competition

Article 267.- Without prejudice to any other right of action, parties interested may request the competent national authority to rule on the lawfulness of any commercial act or practice pursuant to the stipulations set out under this Title.

Article 268.- The right of action for unfair competition pursuant to this Title shall lapse two years following the last practice of the unfair act, unless domestic law stipulates a different time-limit.

Article 269.- The competent national authority may initiate ex officio the proceedings for unfair competition provided for in the legislation of the Member Country concerned, if that legislation allows for it.

FINAL PROVISIONS

Article 270.- The Member Countries, with the support of the General Secretariat, shall set up an Andean information system on the intellectual property rights registered in each of those countries and to that end, shall interconnect their respective databases by December 31, 2002 at the latest.

Article 271.- The Member Countries shall undertake the establishment of mechanisms for disseminating and disclosing the technological know-how contained in investment patents.

Article 272.- The Member Countries shall seek to sign cooperation agreements designed to strengthen the institutional capacity of the competent national offices.

Article 273.- For the purposes of this Decision, a Competent National Office shall be understood to mean the administrative body responsible for the registration of Intellectual Property.

The Competent National Authority, likewise, shall be understood to mean the body designated for that purpose by national legislation on the subject.

Article 274.- This Decision shall take effect on December 1, 2000.

COMPLEMENTARY PROVISIONS

Article 275.- In accordance with the third complementary provision of Decision 391, the competent national authority on matters of access to genetic resources and the competent national offices shall set up systems to exchange information on authorized contracts for access and intellectual property rights granted by December 31, 2001 at the latest.

Article 276.- Intellectual Property matters not covered by this Decision shall be regulated by the domestic legislation of the Member Countries.

Article 277.- The competent national offices may establish such fees as they deem necessary for the handling of the procedures referred to in this Decision.

Once the formalities have been initiated with the competent national offices in question, the fees shall not be refunded.

Article 278.- With a view to the consolidation of a system of community administration, the Member Countries undertake to ensure the best implementation of the provisions contained in this Decision. They likewise commit themselves to strengthen, promote the autonomy of, and modernize the competent national offices and the state-of-the-art information systems and services related to the state of the art

The competent national offices shall send their respective intellectual property gazettes or bulletins to the competent national offices of the other Member Countries as soon as possible following the publication thereof, by any means whatsoever. These gazettes or bulletins shall be made available to the public for consultation at the receiving office.

Article 279.- The Member Countries may sign cooperation agreements on intellectual property, such as the Patent Cooperation Trenty, provided that said agreements do not contravene the provisions of this Decision.

Article 280.- If the domestic law of the Member Countries so orders, parties applying for a patent on a genetically modified organism (GMO) and/or the technological process by which a GMO) is produced, shall also be requested to present a copy of the document issued by the competent national authority on biosafety in each Member Country, granting them permission to produce such a body.

TRANSITIONAL PROVISIONS

FIRST.- Any intellectual property right validly conferred under Andean Community legislation existing prior to the entry into force of this Decision shall be governed by the provisions that were applicable on the grant date, except in regard to the terms of validity, in which case preexisting intellectual property rights shall be adjusted to the provisions stipulated in this Decision.

The provisions contained in this Decision shall be applicable with respect to use and exercise, obligations, licensing, renewal, and extensions.

In the case of applications being processed, this Decision shall be applicable to such stages as have not yet been completed on the date of its entry into effect.

SECOND.- Microorganisms shall be patentable until other measures are adopted as a result of the examination provided for in TRIPS article 27 3b).

The commitments assumed by the Member Countries under the Convention on Biological Diversity shall be borne in mind in this regard.

THIRD.- The competent national offices shall, as stipulated in article 278, interconnect their databases by December 31, 2002, at the latest. The General Secretariat shall apply for international technical and financial resources for this purpose.

Signed in the city of Lima, Peru on the fourteenth of September of two thousand.

REPUBLICA DE COLOMBIA
Ministerio de Relaciones Exteriores

DAM/CAA 39914 ___

Bogotá D.C., 29 de octubre de 2002

31981
NOV 13 2002
ACTION HM
FILE
INFO VN, FV, OJ

Señor
Hamdallah Zedan
Secretario Ejecutivo
Convenio de Diversidad Biológica
Montreal

Señor Secretario Ejecutivo:

Por medio de la presente y en atención a la Notificación SCBD/SEL/VN del 27 de junio de 2002, remito la siguiente información relacionada con el consentimiento informado previo de las comunidades indígenas y locales en Colombia:

- Decreto 1397 de 8 de agosto de 1996 mediante el cual se crea la Comisión Nacional de Territorios Indígenas y la Mesa Permanente de Concertación con los Pueblos y Organizaciones Indígenas.
- Decreto 1320 del 13 de julio de 1998, por el cual se reglamenta la consulta previa con las comunidades indígenas y negras para la exploración de los recursos naturales dentro de su territorio.

Atentamente,

LUZ STELLA JARA PORTILLA
Directora de Asuntos Económicos, Sociales y Ambientales Multilaterales (E)

Anexos: lo anunciado

República de Colombia

Ministerio del Interior
Secretaría General

Revisó: GM

Aprobó:

Decreto Número (1320) de 19

13 JUL. 1990

88-413

"Por el cual se reglamenta la consulta previa con las comunidades indígenas y negras para la explotación de los recursos naturales dentro de su territorio"

EL PRESIDENTE DE LA REPÚBLICA DE COLOMBIA

En uso de sus atribuciones constitucionales y legales, en especial de las que le confiere el numeral 11 del artículo 189 y el parágrafo del artículo 330 de la Constitución Política, en desarrollo de lo dispuesto en el numeral 2o. del artículo 15 de la ley 21 de 1991, en el artículo 44 de la ley 70 de 1993 y en el artículo 76 de la ley 99 de 1993,

CONSIDERANDO

Que el artículo 7o. de la Constitución Política señala que: "El Estado reconoce y protege la diversidad étnica y cultural de la Nación colombiana".

Que el parágrafo del artículo 330 de la Constitución Política establece: "La explotación de los recursos naturales en los territorios indígenas se hará sin desmedro de la integridad cultural, social y económica de las comunidades indígenas. En las decisiones que se adopten respecto de dicha explotación el Gobierno propiciará la participación de los representantes de las respectivas comunidades".

Que el numeral 3o. del artículo 7o. de la ley 21 de 1991, por la cual se aprueba el Convenio No. 169 de 1987 de la O.I.T. sobre pueblos indígenas y tribales, dispone que "Los gobiernos deberán velar porque, siempre que haya lugar, se efectúen estudios, en cooperación con los pueblos interesados, a fin de evaluar la incidencia social, espiritual y cultural y sobre el medio ambiente que las actividades de desarrollo previstas puedan tener sobre esos pueblos. Los resultados de estos estudios deberán ser considerados como criterios fundamentales para la ejecución de las actividades mencionadas".

Que igualmente, el numeral 2 del artículo 15 de la ley 21 de 1991 establece que: "En caso de que pertenezca al Estado la propiedad de los minerales o recursos del subsuelo, o tenga derechos sobre otros recursos existentes en las tierras, los gobiernos deberán establecer o mantener procedimientos con miras a consultar a los pueblos interesados, a fin de determinar si los intereses de esos pueblos serían perjudicados y en qué medida, antes de emprender o autorizar cualquier programa de prospección o explotación de los recursos existentes en sus tierras..."

Que el artículo 17 de la ley 70 de 1993 preceptúa que a partir de su vigencia y hasta tanto no se haya adjudicado en debida forma la propiedad colectiva a una comunidad negra que [illegible] se adjudicarán las tierras

Decreto No. 1320 de 19 Hoja No.

Continuación del Decreto "Por el cual se reglamenta la consulta previa con las comunidades indígenas y negras para la explotación de los recursos naturales dentro de su territorio". Pág 2

Que el artículo 35 del Decreto 1745 de 1995 sobre elementos básicos para el concepto previo por parte de la Comisión Técnica, en su numeral 1° establece que esta Comisión verificará "Si el proyecto objeto de la solicitud de otorgamiento de licencia ambiental, concesión, permiso, autorización o de celebración de contratos de aprovechamiento y explotación de los recursos naturales y genéticos (sic), se encuentra en zonas susceptibles de ser tituladas como tierras de comunidades negras, a fin de hacer efectivo el derecho de prelación de que trata la ley"

Que de igual forma, el artículo 44 de la ley 70 de 1993 establece "Como un mecanismo de protección de la identidad cultural, las comunidades negras participarán en el diseño, elaboración y evaluación de los estudios de impactos ambiental, socioeconómico y cultural, que se realicen sobre los proyectos que se pretendan adelantar en las áreas a que se refiere esta ley".

Que el artículo 76 de la ley 99 de 1993 estipula que "La explotación de los recursos naturales deberá hacerse sin desmedro de la integridad cultural, social y económica de las comunidades indígenas y de las negras tradicionales de acuerdo con la ley 70 de 1993 y el artículo 330 de la Constitución Nacional, y las decisiones sobre la materia se tomarán, previa consulta a los representantes de tales comunidades"

Que se hace necesario reglamentar de manera especial la consulta previa a las comunidades indígenas y negras tradicionales mediante un procedimiento específico que permita a las autoridades ambientales ejercer su competencia en esa materia y cumplir el mandato contenido en el artículo 76 de la ley 99 de 1993,

DECRETA

CAPÍTULO I

DISPOSICIONES GENERALES

ARTÍCULO 1o. OBJETO. La consulta previa tiene por objeto analizar el impacto económico, ambiental, social y cultural que puede ocasionarse a una comunidad indígena o negra por la explotación de recursos naturales dentro de su territorio, conforme a la definición del artículo 2º del presente decreto, y las medidas propuestas para proteger su integridad.

ARTÍCULO 2o. DETERMINACIÓN DE TERRITORIO. La consulta previa se realizará cuando el proyecto, obra o actividad se pretenda desarrollar en zonas de resguardo o reservas indígenas o en zonas adjudicadas en propiedad colectiva a comunidades negras. Igualmente, se realizará consulta previa cuando el proyecto, obra o actividad se pretenda desarrollar en zonas no tituladas y habitadas en forma regular y permanente por dichas comunidades indígenas o negras, de conformidad con lo establecido en el siguiente artículo.

ARTÍCULO 3o. IDENTIFICACIÓN DE COMUNIDADES INDÍGENAS Y NEGRAS. Cuando el proyecto, obra o actividad se pretenda realizar en zonas no tituladas y habitadas en forma regular y permanente por comunidades indígenas o negras susceptibles de ser

geográfica.: El Instituto Colombiano para la Reforma Agraria - INCORA - certificará sobre la existencia de territorio legalmente constituido.

Las anteriores entidades, expedirán dicha certificación dentro de los quince (15) días hábiles siguientes a la radicación de la solicitud que para el efecto haga el interesado en el proyecto, obra o actividad, la cual contendrá:

a) Identificación del interesado;

a. Fecha de la solicitud;

b. Breve descripción del proyecto, obra o actividad;

c. Identificación del área de influencia directa del proyecto, obra o actividad, acompañada de un mapa que precise su localización con coordenadas geográficas o con sistema Gauss.

PARÁGRAFO 1o. De no expedirse las certificaciones por parte de las entidades previstas en este artículo, en el término señalado, podrán iniciarse los estudios respectivos. No obstante, si durante la realización del estudio el interesado verifica la presencia de tales comunidades indígenas o negras dentro del área de influencia directa de su proyecto, obra o actividad, deberá integrarlas a los estudios correspondientes, en la forma y para los efectos previstos en este Decreto e informará al Ministerio del Interior para garantizar la participación de tales comunidades en la elaboración de los respectivos estudios.

PARÁGRAFO 2o. En caso de existir discrepancia en torno a la identificación del área de influencia directa del proyecto, obra o actividad, serán las autoridades ambientales competentes quienes lo determinen.

PARÁGRAFO 3o. Las certificaciones de que trata el presente artículo se expedirán transitoriamente, mientras el Ministerio del Interior en coordinación con el Instituto Geográfico Agustín Codazzi – IGAC- y el Instituto Colombiano para la Reforma Agraria – INCORA-, elaboran una cartografía georeferenciada a escala apropiada respecto de las áreas donde existan comunidades indígenas o negras de las que trata la ley 70 de 1993, en los términos de ocupación territorial de que tratan los artículos 2° y 3° del presente Decreto. Para este efecto, dichas entidades dispondrán de un término de seis (6) meses contados a partir de la expedición del presente Decreto. La cartografía de que trata este parágrafo deberá ser actualizada cada seis (6) meses.

ARTÍCULO 4o. EXTENSIÓN DEL PROCEDIMIENTO. Cuando los estudios ambientales determinen que de las actividades proyectadas se derivan impactos económicos, sociales o culturales sobre las comunidades indígenas o negras, de conformidad con las definiciones de este Decreto y dentro del ámbito territorial de los artículos 2° y 3° del mismo, se aplicará el procedimiento establecido en los artículos siguientes.

CAPITULO IV

CONSULTA PREVIA EN MATERIA DE LICENCIAS AMBIENTALES O ESTABLECIMIENTO DE PLANES DE MANEJO AMBIENTAL

de 19 , Hoja No.

ARTÍCULO 5o. PARTICIPACIÓN DE LAS COMUNIDADES INDÍGENAS Y NEGRAS EN LA ELABORACIÓN DE LOS ESTUDIOS AMBIENTALES. El responsable del proyecto, obra o actividad que deba realizar consulta previa, elaborará los estudios ambientales con la participación de los representantes de las comunidades indígenas o negras.

Para el caso de las comunidades indígenas con la participación de los representantes legales o las autoridades tradicionales y frente a las comunidades negras con la participación de los miembros de la Junta del Consejo Comunitario o, en su defecto, con los líderes reconocidos por la comunidad de base.

El responsable del proyecto, obra o actividad acreditará con la presentación de los estudios ambientales, la forma y procedimiento en que vinculó a los representantes de las comunidades indígenas y negras en la elaboración de los mismos, para lo cual deberá enviarles invitación escrita

Transcurridos veinte (20) días de enviada la invitación sin obtener respuesta de parte de los pueblos indígenas o comunidades negras, el responsable del proyecto, obra o actividad informará al Ministerio del Interior para que verifique dentro de los diez (10) días siguientes al recibo de la comunicación, si existe voluntad de participación de los representantes de dichas comunidades y lo informará al interesado

En caso que los representantes de las comunidades indígenas y/o negras se nieguen a participar, u omitan dar respuesta dentro de los términos antes previstos, el interesado elaborará el estudio ambiental prescindiendo de tal participación

ARTÍCULO 6o. TÉRMINOS DE REFERENCIA. Dentro de los términos de referencia que expida la autoridad ambiental para la elaboración de los estudios ambientales se incluirán los lineamientos necesarios para analizar el componente socioeconómico y cultural de las comunidades indígenas o negras.

ARTÍCULO 7o. PROYECTOS QUE CUENTAN CON TÉRMINOS DE REFERENCIA GENÉRICOS. Cuando el proyecto, obra o actividad, cuente con términos de referencia genéricos expedidos por la autoridad ambiental respectiva, el interesado deberá informar al Ministerio del Interior sobre la participación de las comunidades indígenas o negras susceptibles de ser afectadas, en la elaboración de los estudios.

ARTÍCULO 8o. SOLICITUD DE LICENCIA AMBIENTAL O DE ESTABLECIMIENTO DEL PLAN DE MANEJO AMBIENTAL. Cuando se pretenda desarrollar un proyecto, obra o actividad dentro del ámbito territorial previsto en los artículos 2° y 3° de este Decreto, a la solicitud de licencia ambiental o de establecimiento del Plan de Manejo Ambiental, se anexarán las certificaciones de que trata el artículo 3° del presente Decreto.

ARTÍCULO 9o. PROYECTOS QUE NO CUENTAN CON TÉRMINOS DE REFERENCIA GENÉRICOS. Recibida la solicitud de términos de referencia y establecida la necesidad de hacer consulta previa, la autoridad ambiental competente al momento de expedirlos, informará al Ministerio del Interior sobre la participación de las comunidades indígenas y/o negras susceptibles de ser afectadas en la elaboración de los estudios

ARTÍCULO 10o. CONTENIDO DE LOS ESTUDIOS AMBIENTALES FRENTE AL COMPONENTE SOCIOECONÓMICO Y CULTURAL. En relación con el componente socioeconómico y cultural, los estudios ambientales deberán contener por lo menos lo siguiente:

1. En el diagnóstico ambiental de alternativas:

Características de la cultura de las comunidades indígenas y/o negras. Este elemento se tendrá en cuenta por parte de la autoridad ambiental para escoger la alternativa para desarrollar el estudio de impacto ambiental.

2 En el estudio de impacto ambiental o plan de manejo ambiental:

a) Características de la cultura de las comunidades indígenas y/o negras.

b) Los posibles impactos sociales, económicos y culturales que sufrirán las comunidades indígenas y/o negras estudiadas, con la realización del proyecto, obra o actividad

c) Las medidas que se adoptarán para prevenir, corregir, mitigar, controlar o compensar los impactos que hayan de ocasionarse.

ARTÍCULO 11o. COMUNICACIÓN A LA COMISIÓN TÉCNICA DE QUE TRATA LA LEY 70 DE 1993. Hasta cuando se adjudique en debida forma la propiedad colectiva de las comunidades negras susceptibles de ser afectadas por el proyecto, obra o actividad, la autoridad ambiental competente remitirá copia del auto de iniciación de trámite a la Comisión Técnica de que trata el artículo 8° de la Ley 70 de 1993, para que emita el concepto exigido en el artículo 17 de la misma ley.

ARTÍCULO 12o. REUNIÓN DE CONSULTA. Dentro de los quince (15) días siguientes a la fecha de la solicitud de licencia ambiental o de establecimiento del Plan de Manejo Ambiental, la autoridad ambiental competente comprobará la participación de las comunidades interesadas en la elaboración del Estudio de Impacto Ambiental, o la no participación, y citará a la reunión de consulta previa que deberá celebrarse dentro de los treinta (30) días siguientes al auto que así lo ordene preferiblemente en la zona donde se encuentre el asentamiento.

Dicha reunión será presidida por la autoridad ambiental competente, y deberá contar con la participación del Ministerio del Interior. En ella deberán participar el responsable del proyecto, obra o actividad y los representantes de las comunidades indígenas y/o negras involucradas en el estudio.

Sin perjuicio de sus facultades constitucionales y legales, podrán ser igualmente invitados la Procuraduría General de la Nación, la Defensoría del Pueblo y las demás entidades del Estado que posean interés en el asunto, de conformidad con la naturaleza del impacto proyectado.

de 19 ... Hoja No.

Continuación del Decreto "Por el cual se reglamenta la consulta previa con las comunidades indígenas y negras para la explotación de los recursos naturales dentro de su territorio" Pág.6

PARÁGRAFO 2o. La reunión se celebrará en idioma castellano, con traducción a las lenguas de las comunidades indígenas y negras presentes, cuando sea del caso. De ella se levantará un acta en la que conste el desarrollo de la misma, que será firmada por los representantes de las comunidades indígenas y negras; igualmente será firmada por los representantes de la autoridad ambiental competente, del Ministerio del Interior y de las autoridades de control que asistan a ella.

ARTÍCULO 13o. DESARROLLO DE LA REUNIÓN En la reunión de consulta se seguirá el siguiente procedimiento:

a) Instalada la reunión y verificada la asistencia, el responsable del proyecto, obra o actividad hará una exposición del contenido del estudio respectivo, con especial énfasis en la identificación de los posibles impactos frente a las comunidades indígenas y a las comunidades negras, y la propuesta de manejo de los mismos.

b) Acto seguido, se escuchará a los representantes de las comunidades indígenas y negras consultadas.

c) Si existe acuerdo en torno a la identificación de impactos y a las medidas propuestas dentro del plan de manejo ambiental, y las demás a que hubiere lugar, según el caso, en lo relacionado con las comunidades indígenas y negras, se levantará la reunión dejando en el acta constancia expresa del hecho.

d) En caso de no existir acuerdo sobre las medidas propuestas dentro del plan de manejo ambiental y las demás a que hubiere lugar, la autoridad ambiental competente suspenderá la reunión por una sola vez, y por el término máximo de 24 horas, con el fin de que las partes evalúen las propuestas. Si después de reanudada la reunión, se llegare a un acuerdo, deberá darse aplicación a lo establecido en el literal anterior; en caso de que continúe el desacuerdo, se procederá de conformidad con el siguiente literal del presente artículo.

e) En caso de no existir acuerdo respecto de las medidas contenidas en el Plan de Manejo Ambiental, se dará por terminada la reunión dejando en el acta constancia expresa de tal hecho y la autoridad ambiental competente decidirá sobre el particular en el acto que otorgue o niegue la licencia ambiental.

f) Si cualquiera de las comunidades indígenas o negras involucradas no asiste a la reunión de consulta, deberá justificar su inasistencia ante la autoridad ambiental, dentro de los ocho (8) días siguientes a la fecha programada para su celebración. En caso de que no exista justificación válida se entenderá que se encuentra de acuerdo con las medidas de prevención, corrección, mitigación, control o compensación de los impactos que se le puedan ocasionar.

g) Justificada la inasistencia, la autoridad ambiental, dentro de los quince (15) días siguientes, citará a una nueva reunión para el efecto.

h) Agotado el objeto de la reunión, la autoridad ambiental competente, la dará por terminada, dejando constancia de lo ocurrido en el acta y continuará con el trámite

CAPÍTULO III

CONSULTA PREVIA FRENTE AL DOCUMENTO DE EVALUACIÓN Y MANEJO AMBIENTAL.

ARTÍCULO 14o. DOCUMENTO DE EVALUACIÓN Y MANEJO AMBIENTAL. Cuando quiera que se den los supuestos del artículo 2° del presente Decreto para los proyectos, obras o actividades cobijados por lo dispuesto en el Decreto 883 de 1997, se deberá realizar la consulta previa con las comunidades indígenas y negras.

En tal caso, el documento de evaluación y manejo ambiental deberá elaborarse de conformidad con lo establecido en los artículos 5° y 10° numeral 2° del presente Decreto. El interesado antes de elaborar el documento de evaluación y manejo ambiental deberá informar al Ministerio del Interior para que constate la participación de las comunidades indígenas o negras susceptibles de ser afectadas en la elaboración de los estudios.

La consulta previa se realizará una vez elaborado el documento de evaluación y manejo ambiental y con anterioridad a la entrega ante la autoridad ambiental competente, en las formas y condiciones establecidas en los artículos 11° y 12° del presente Decreto. Para tal fin se deberá dar aviso oportunamente a la autoridad ambiental competente.

Dentro de los diez (10) días siguientes a la presentación del documento de evaluación y manejo ambiental, la autoridad ambiental competente se pronunciará indicando si es procedente o no dar inicio a las obras.

CAPÍTULO IV

CONSULTA PREVIA EN MATERIA DE PERMISOS DE USO, APROVECHAMIENTO O AFECTACIÓN DE RECURSOS NATURALES RENOVABLES

ARTÍCULO 15o. PERMISOS DE USO, APROVECHAMIENTO O AFECTACIÓN DE RECURSOS NATURALES RENOVABLES. Cuando se pretenda desarrollar un proyecto, obra o actividad dentro del ámbito territorial previsto en los artículos 2° y 30 de este Decreto, a la solicitud presentada ante la autoridad ambiental competente para acceder al uso, aprovechamiento o afectación de los recursos naturales renovables que no vayan implícitos dentro de una licencia ambiental, se anexarán las certificaciones de que trata el artículo 3o. del presente Decreto.

Recibida la solicitud y establecida la necesidad de hacer consulta previa, la autoridad ambiental competente informará al Ministerio del Interior para efectos de su coordinación. Igualmente, la autoridad ambiental competente deberá dar aplicación a lo dispuesto en el artículo 11° de este Decreto cuando sea del caso.

ARTÍCULO 16o. REUNIÓN DE CONSULTA. Dentro de los quince (15) días siguientes a la fecha de recibo de la solicitud de aprovechamiento, uso o afectación de los recursos naturales renovables, la autoridad ambiental competente citará a una reunión de consulta, que deberá celebrarse dentro de los quince (15) días siguientes al auto que así lo ordena,

Deberá participar en tal reunión, el interesado, los representantes de las comunidades indígenas y negras involucradas y el Ministerio del Interior; igualmente serán invitados a asistir la Procuraduría General de la Nación y la Defensoría del Pueblo. Podrán asistir también, otras entidades del Estado que posean interés en el asunto.

ARTÍCULO 17o. DESARROLLO DE LA REUNIÓN DE CONSULTA. La reunión de consulta se desarrollará de la siguiente manera:

a)Instalada la reunión y verificada la asistencia, el interesado expondrá las condiciones técnicas en que pretende usar, aprovechar o afectar los recursos naturales renovables.

b)Acto seguido se escuchará a los representantes de las comunidades indígenas o negras consultadas y se determinarán los impactos que se pueden generar con ocasión de la actividad y las medidas necesarias para prevenirlos, corregirlos, mitigarlos, controlarlos o compensarlos.

c)En esta reunión se aplicará lo dispuesto en los literales f) y g) del artículo 13 del presente Decreto.

d)Agotado el objeto de la reunión, la autoridad ambiental competente la dará por terminada, dejando constancia de lo ocurrido en el acta y continuará con el trámite establecido en las normas vigentes, con el objeto de tomar una decisión sobre el otorgamiento o negación del permiso de uso, aprovechamiento o afectación de los recursos naturales renovables.

ARTÍCULO 18o: AMBITO DE APLICACIÓN: Las disposiciones contenidas en los capítulos III y IV del presente Decreto no se aplicarán cuando se trate de licencias ambientales que contengan permisos, concesiones y autorizaciones para el aprovechamiento de los recursos naturales.

CAPÍTULO V

DISPOSICIONES FINALES

ARTÍCULO 19o. COMUNICACIÓN DE LA DECISIÓN. El acto administrativo que otorgue o niegue la licencia ambiental, el establecimiento del plan de manejo ambiental o el permiso de uso, aprovechamiento o afectación de los recursos naturales renovables deberá ser comunicado a los representantes de las comunidades indígenas y negras consultadas.

ARTÍCULO 20o. RÉGIMEN TRANSITORIO. Las consultas previas con comunidades indígenas o negras cuyo trámite se hubiere iniciado con anterioridad a la vigencia del presente Decreto, continuarán su desarrollo en la forma acordada. No obstante, el interesado en el proyecto, obra o actividad podrá optar por la sujeción al procedimiento establecido en este Decreto.

ARTÍCULO 21o. MECANISMOS DE SEGUIMIENTO. Sin perjuicio de la plena vigencia del presente Decreto a partir de la fecha de su publicación, dentro de los seis (6) meses siguientes a ella el Gobierno Nacional propiciará con las comunidades indígenas y negras

Continuación del Decreto "Por el cual se reglamenta la consulta previa con las comunidades indígenas y negras para la explotación de los recursos naturales dentro de su territorio". Pág.9

ARTÍCULO 22o. VIGENCIA. El presente Decreto rige a partir de la fecha de su publicación y deroga todas las disposiciones que le sean contrarias.

PUBLÍQUESE Y CÚMPLASE
Dado en Santafé de Bogotá D. C., a los 13 JUL 1998

EL MINISTRO DEL INTERIOR,

ALFONSO LÓPEZ CABALLERO

EL MINISTRO DE AGRICULTURA,

ANTONIO GÓMEZ MERLANO

EL MINISTRO DE MINAS Y ENERGÍA,

ORLANDO CABRALES MARTÍNEZ

EL VICEMINISTRO DEL MEDIO AMBIENTE, ENCARGADO DE LAS FUNCIONES DEL DESPACHO DEL MINISTRO DEL MEDIO AMBIENTE,

FABIO ARJONA HINCAPIÉ

Ministerio del Interior
Secretaría General

Decreto Número 1397 de 1996

- 8 AGO. 1996

Por el cual se crean la Comisión Nacional de Territorios Indígenas y la Mesa Permanente de Concertación con los Pueblos y Organizaciones Indígenas y se dictan otras disposiciones

El Presidente de la República de Colombia,

en uso de las facultades que le concede el numeral 11 del artículo 189 de la Constitución Política, en virtud de lo dispuesto por la Ley 21 de 1991 y el artículo 1o. del Decreto-Ley 1050 de 1968 y en cumplimiento del parágrafo del artículo 330 de la Constitución Política,

DECRETA:

ARTICULO 1o. COMISION NACIONAL DE TERRITORIOS INDIGENAS. Créase la Comisión Nacional de Territorios Indígenas, adscrita al Ministerio de Agricultura y Desarrollo Rural, integrada por:

1. El Viceministro de Desarrollo Rural Campesino del Ministerio de Agricultura y Desarrollo Rural o su delegado;

2. El Gerente General del INCORA o su delegado;

3. El Subgerente de Planeación del INCORA;

4. El Jefe de la División para la Atención de Comunidades Indígenas y Negras del INCORA;

5. Un delegado del Ministro del Interior;

6. El Jefe de la Unidad de Desarrollo Agropecuario del Departamento Administrativo de Planeación Nacional;

7. El Director General del Presupuesto del Ministerio de Hacienda y Crédito Público o su delegado;

8. El Presidente de la Organización Nacional Indígena de Colombia ONIC o un delegado por el Comité Ejecutivo;

9. El presidente de la Organización de Pueblos Indígenas de la Amazonia Colombiana OPIAC o un delegado por el Comité Ejecutivo;

10. Un delegado por la Confederación Indígena Tairona;

11. Un delegado por cada macrorregión CORPES o las Regiones Administrativas de Planificación que se conformen de acuerdo con el artículo 306 de la Constitución Política, seleccionados por las organizaciones indígenas de la respectiva región.

PARAGRAFO. Los Senadores Indígenas y los exconstituyentes indígenas serán invitados permanentes a la Comisión Nacional de Territorios Indígenas.

ARTICULO 2o. FUNCIONES. La Comisión Nacional de Territorios Indígenas tendrá las siguientes funciones:

1. Acceder a la información consolidada sobre gestión del INCORA respecto de Resguardos Indígenas durante el período 1980 - 1996.

2. Acceder a la información y actualizarla, sobre necesidades de las comunidades indígenas para la constitución, ampliación, reestructuración y saneamiento de Resguardos y Reservas Indígenas y la conversión de éstas en Resguardo; solicitudes presentadas, expedientes abiertos y estado de los procedimientos adelantados.

3. Concertar la programación para períodos anuales de las acciones de constitución, ampliación, reestructuración y saneamiento de Resguardos y saneamiento y conversión de Reservas Indígenas que se requieran de acuerdo con la información a que se refiere el numeral anterior, para su ejecución a partir de la vigencia presupuestal de 1997, priorizando las siguientes:

   a. Saneamiento de Resguardos Indígenas constituidos en las zonas de Reserva Forestal de la Amazonia y del Pacífico dentro del plazo establecido en el Parágrafo 4o. del artículo 85 de la Ley 160 de 1994.

   b. Ampliación, constitución y/o saneamiento de Resguardos para pueblos indígenas amenazados: Chimila, Nukak, Yukpas, Kofan, Embera de Risaralda (Caldas), pueblos indígenas de Arauca, la comunidad Kuti del Río Tolo en el Departamento del Chocó y la Conversión de Reservas en resguardos y su saneamiento.

   c. Para las comunidades indígenas del Tolima: Constitución de Resguardos en los predios del Fondo Nacional Agrario que hayan sido entregados y los que posean tradicionalmente; y adelantar el programa de adquisición de tierras.

4. Preparar un estimativo de los costos por períodos anuales de las actividades programadas de acuerdo con el numeral anterior, para realizar los estudios socio-económicos, adquisición de predios y mejoras, adecuación institucional, requerimientos técnicos, inscripción de títulos, etc. y señalar los presupuestos necesarios para cada una de las vigencias fiscales.

Continuación ... lo. "Por el cual se crean la Comisión Nacional de Territorios Indígenas y la Mesa Permanente de Concertación con los Pueblos y Organizaciones Indígenas y se dictan otras disposiciones"

5. Presentar al Gobierno Nacional la partida necesaria para la ejecución del cronograma durante el primer año para que este gestione en el Congreso de la República su inclusión en el Proyecto de Ley de Presupuesto, vigencia fiscal de 1997.

6. Bajo el criterio de la obligación del Estado de proteger la diversidad étnica y cultural de la nación y del ordenamiento de los territorios indígenas, analizar las normas de la legislación agraria atinentes a Resguardos Indígenas y recomendar las modificaciones que se requieran para superar los principales obstáculos que se presentan a fin de darle cumplimiento a la constitución, ampliación, saneamiento y reestructuración de Resguardos Indígenas y el saneamiento y conversión de Reservas Indígenas.

7. Recomendar las modificaciones que requiera el Acuerdo 13 de 1995 de la Junta Directiva del INCORA y presentarlo para su aprobación.

8. Hacer el seguimiento a la ejecución de la programación del INCORA para la constitución, ampliación, saneamiento y reestructuración de Resguardos Indígenas, y saneamiento y conversión de Reservas a partir de la fecha de expedición del presente Decreto.

PARAGRAFO 1o. El cumplimiento de los compromisos adquiridos en desarrollo de los convenios o acuerdos suscritos por el Gobierno o el INCORA, con organizaciones o pueblos indígenas, se hará conforme a los cronogramas y demás contenidos de los acuerdos.

PARAGRAFO 2o. Para el cumplimiento de las funciones de que tratan los numerales 1, 2, 3, 4 y 7 del presente artículo la Comisión Nacional de Territorios Indígenas dispondrá del término de cuatro (4) meses a partir de la fecha de expedición del presente Decreto.

ARTICULO 3o. APROPIACION PRESUPUESTAL. El Gobierno Nacional incluirá anualmente en el Proyecto de Ley de Presupuesto, las partidas necesarias para la ejecución de la programación de que trata el numeral 3 de conformidad con el estimativo de costos de que trata el numeral 4 del mismo artículo y de acuerdo con los procedimientos determinados por las normas vigentes.

ARTICULO 4o. PROPUESTA ECONOMICA Y OPERATIVA. La Comisión Nacional de Territorios Indígenas preparará una propuesta para agilizar los trámites para la constitución, ampliación, saneamiento y reestructuración de Resguardos Indígenas y el saneamiento y conversión de Reservas Indígenas con destino al INCORA y demás instituciones del Estado que intervengan en los procedimientos anteriores.

Cuando el INCORA requiera contratar profesionales, técnicos y promotores para la realización de estudios socio económicos u otras labores relacionadas con comunidades indígenas, concertará con éstas y sus autoridades y organizaciones los términos de referencia y el perfil del personal.

La Comisión gestionará ante las entidades competentes todas las medidas necesarias para la defensa y protección de la integridad de los Territorios Indígenas.

Continuación del Decreto, "Por el cual se crean la Com... Indígenas y la Mesa Permanente de Concertación con l... Indígenas y se dictan otras disposiciones"

ARTICULO 5o. SOPORTE. El Ministerio de Agricultura y Desarrollo Rural, el INCORA y el Departamento Nacional de Planeación suministrarán a la Comisión el apoyo técnico, informativo y logístico que sea necesario para el cumplimiento de sus funciones en los términos estipulados en este Decreto.

ARTICULO 6o. CONCERTACION. Para los efectos del presente decreto, la concertación se hará en concordancia con lo dispuesto por la Constitución Política de Colombia, los Instrumentos Internacionales que obligan a Colombia, así como las leyes 160 de 1994, 191 y 199 de 1995 y demás normas que garantizan los derechos de los Pueblos Indígenas.

ARTICULO 7o. LICENCIAS AMBIENTALES. No se podrá otorgar ninguna licencia ambiental sin los estudios de impacto económico, social y cultural sobre los pueblos o comunidades indígenas, los cuales harán parte de los estudios de impacto ambiental. Los estudios se realizarán con la participación de las comunidades, sus autoridades y organizaciones.

Cuando de los estudios, o a consideración de la autoridad ambiental o del seguimiento con la participación de las comunidades afectadas, sus autoridades y organizaciones, se desprenda que se puede causar o se está causando desmedro a la integridad económica, social o cultural de los pueblos o comunidades indígenas, se negarán, suspenderán o revocarán las licencias, mediante resolución motivada.

ARTICULO 8o. OBRAS E INVERSIONES. Ninguna obra, exploración, explotación o inversión podrá realizarse en Territorio Indígena sin la previa concertación con las autoridades indígenas, comunidades y sus organizaciones.

ARTICULO 9o. ADQUISICION DE PREDIOS. En el término de un mes a partir de la expedición del presente Decreto, la Junta Directiva del INCORA revisará y hará las modificaciones que requiera el Acuerdo 13 de 1995 para ponerlo en consonancia con el Decreto 2164 de 1995 en lo relativo a procedimientos de constitución, ampliación, reestructuración o saneamiento de resguardos y la conversión de Reservas Indígenas en Resguardos.

ARTICULO 10. MESA DE CONCERTACION. Créase la Mesa Permanente de Concertación con los Pueblos y Organizaciones Indígenas, adscrita al Ministerio del Interior, integrada por los siguientes miembros permanentes:

- El Ministro del Interior o su delegado;
- El Ministro de Agricultura y Desarrollo Rural o su delegado;
- El Ministro del Medio Ambiente o su delegado;
- El Ministro de Hacienda y Crédito Público o su delegado;
- El Ministro de Desarrollo Económico o su delegado;
- El Ministro de Minas y Energía o su delegado;

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- El Ministro de Educación Nacional o su delegado;
- El Director del Departamento Nacional de Planeación o su delegado;
- El Consejero Presidencial de Fronteras o su delegado;
- El Consejero Presidencial de Política Social o su delegado;
- Los Senadores Indígenas;
- Los exconstituyentes indígenas;
- El Presidente de la Organización Nacional Indígena de Colombia ONIC o un delegado por el Comité Ejecutivo;
- El presidente de la Organización de Pueblos Indígenas de la Amazonia Colombiana OPIAC o un delegado por el Comité Ejecutivo;
- Un delegado por la Confederación Indígena Tairona;
- Un delegado por cada macrorregión CORPES o las Regiones Administrativas de Planificación que se conformen de acuerdo con el artículo 306 de la Constitución Nacional, seleccionados por las organizaciones indígenas de la respectiva región.

PARAGRAFO. El Gobierno Nacional invitará como integrantes permanentes a la mesa de concertación en calidad de veedores a la Organización Internacional del Trabajo, a la Comisión Interamericana de Derechos Humanos y a la Conferencia Episcopal de Colombia para que realice el seguimiento, impulso, vigilancia y divulgación al cumplimiento de las funciones de la Mesa de Concertación y de los acuerdos a que se llegue. Los miembros indígenas de la Mesa de Concertación podrán invitar a participar en sus deliberaciones o en las Comisiones Temáticas a los asesores que designen.

ARTICULO 11. OBJETO. La Mesa Permanente de Concertación con los Pueblos y Organizaciones Indígenas tendrá por objeto concertar entre éstos y el Estado todas las decisiones administrativas y legislativas susceptibles de afectarlos, evaluar la ejecución de la política indígena del Estado, sin perjuicio de las funciones del Estado, y hacerle seguimiento al cumplimiento de los acuerdos a que allí se lleguen.

ARTICULO 12. FUNCIONES. La Mesa Permanente de Concertación, además de lo dispuesto en el artículo anterior, cumplirá las siguientes funciones:

1. Adoptar principios, criterios y procedimientos en relación con biodiversidad, recursos genéticos, propiedad intelectual colectiva y derechos culturales asociados a estos, en el marco de la legislación especial de los pueblos indígenas.

2. Concertar previamente con los pueblos y organizaciones indígenas las posiciones y propuestas oficiales para proteger los derechos indígenas en materia de acceso a recursos genéticos, biodiversidad y protección del conocimiento colectivo, innovaciones y prácticas [illegible] colombiano en instancias internacionales o en el

3. Concertar el desarrollo de los derechos constitucionales indígenas en relación con biodiversidad, recursos genéticos, propiedad intelectual colectiva y derechos culturales asociados a estos y la legislación ambiental.

4. Concertar el proyecto de Ley que modifica el Código de Minas con el fin de guantizar los derechos de los pueblos indígenas; definir el cronograma, los procedimientos y los presupuestos necesarios para la delimitación de zonas mineras indígenas de acuerdo con las solicitudes de las comunidades y hacerle seguimiento a su ejecución, de conformidad con lo dispuesto en el Decreto 2655 de 1988. La delimitación de las zonas mineras indígenas se hará concertadamente con las organizaciones nacional, regional y las autoridades indígenas del respectivo territorio.

5. Revisar los permisos y licencias otorgados sobre territorios indígenas y los que estén en trámite y solicitar su suspensión o revocatoria cuando sean violatorios de los derechos de los pueblos indígenas de conformidad con la legislación especial.

6. Concertar las partidas presupuestales que se requieran para capacitación, estudios técnicos, asesoría y financiación de proyectos con destino a las comunidades indígenas.

7. Concertar el Decreto Reglamentario de los artículos 2°,3°, 5°, 8°, 9°, 10°, 12°, 13° y el parágrafo 2° del artículo 7°, de la Ley 191 de 1995 con los pueblos y comunidades indígenas de frontera, sus autoridades y organizaciones regionales y nacionales respectivas.

8. Preparar los procedimientos necesarios para acordar entre los pueblos y organizaciones indígenas la propuesta de reglamentación del derecho de participación y concertación de las decisiones administrativas y legislativas susceptibles de afectar a los pueblos indígenas de acuerdo con las particularidades de cada uno, y concertar la expedición del decreto.

9. Concertar el procedimiento transitorio y lo demás que se requiera para la participación, consulta y concertación con pueblos o comunidades indígenas específicos, mientras se expide el decreto reglamentario. La concertación se hará respetando los usos y costumbres de cada pueblo.

10. Abrir un proceso de difusión, análisis y discusión de la Ley No. 100 de 1993 con las organizaciones y comunidades indígenas para que se puedan tomar decisiones de interés y protección de los derechos de los pueblos indígenas; concertar las modificaciones y reglamentaciones pertinentes e involucrarlas en su ejecución. El Gobierno garantizará los recursos para adelantar este proceso a través de las organizaciones.

11. Revisar los decretos 1088 de 1993 y 1407 de 1991 sobre Autoridades Indígenas y sus Asociaciones y las Fundaciones y Corporaciones que trabajan en territorios indígenas, respectivamente, de acuerdo a la diversidad étnica y cultural y concertar sus modificaciones

12. Definir los procedimientos y términos de referencia para la evaluación de la estructura estatal para la atención de pueblos indígenas y concertar las decisiones que se requieran de acuerdo con los resultados de la misma.

creto, "Por el cual se crean la Comisión Nacional de Territorios Indígenas y la Mesa Permanente de Concertación con los Pueblos y Organizaciones Indígenas y se dictan otras disposiciones"

13. Concertar un proceso de difusión, análisis y discusión de la Ley No. 218 de 1995 o Ley Páez con las comunidades indígenas y sus organizaciones para que se puedan tomar decisiones de interés y protección de los derechos de los pueblos indígenas; concertar los proyectos de ley para su modificación en lo que se requiera, y su reglamentación. El Gobierno garantizará los recursos para adelantar este proceso a través de las organizacione . En la reglamentación de la Ley se garantizará que personas externas a la región no abusen de los beneficios de la Ley.

14. Hacer seguimiento a la ejecución de la Inversión Social y Ambiental para los pueblos indígenas dispuesta por la Ley del Plan Nacional de Desarrollo; acordar las medidas necesarias para garantizar la destinación y ejecución del 2% anual de la inversión social y ambiental para los pueblos indígenas en los términos dispuestos en los artículos 29 y 42 de la ley 188 de 1995 y para el cumplimiento de los compromisos adquiridos por el Gobierno Nacional con pueblos, comunidades u organizaciones indígenas. El Gobierno unificará y simplificará los trámites, requisitos y fichas de acceso a los fondos de cofinanciación, previa concertación en la Mesa de que trata este decreto.

Igualmente se concertará el seguimiento para agilizar y garantizar la ejecución de los recursos de la vigencia fiscal de 1996.

15. Concertar los proyectos de Ley y decretos reglamentarios relativos a las transferencias de Ingresos Corrientes de la Nación a los Resguardos indígenas y hacer seguimiento al cumplimiento de los mismos.

16. Concertar lo relativo al desarrollo de las competencias otorgadas por el Artículo Transitorio 56 de la Constitución al Gobierno Nacional y todo lo relacionado con el ordenamiento territorial indígena.

17. Revisar las normas relativas a la educación propia de los pueblos indígenas y concertar sus modificaciones y reglamentación, y vigilar su cumplimiento.

18. Acordar medidas para garantizar y supervisar la aplicación del decreto 1811 de 1991.

19. Darse su propio reglamento de conformidad con lo regulado por este decreto.

PARAGRAFO. Las concertaciones de la Mesa relacionadas con temas objeto de otras comisiones creadas a la fecha de expedición del presente decreto, serán presentadas a éstas por el Gobierno Nacional.

ARTICULO 13. COMISIONES TEMATICAS. Los integrantes permanentes de la Mesa de Concertación organizarán por temas y asuntos específicos comisiones de trabajo y concertación con participación de las entidades oficiales de acuerdo con sus competencias constitucionales y legales y con participación de delegados de los miembros indígenas de la Mesa. En las Comisiones Temáticas participarán los delegados de los pueblos, autoridades y organizaciones indígenas directamente interesados o afectados cuando se traten temas específicos de sus comunidades o regiones.

Continuación del Decreto, "Por el cual se crean la Comisión Nacional de Territorios Indígenas y la Mesa Permanente de Concertación con los Pueblos y Organizaciones Indígenas y se dictan otras disposiciones"

ARTICULO 14. AUTONOMIA INDIGENA. Las Autoridades no indígenas respetarán la autonomía de los pueblos, autoridades y comunidades indígenas y no intervendrán en la esfera del gobierno y de la jurisdicción indígenas.

ARTICULO 15. SERVICIO MILITAR. El Gobierno garantizará la permanencia y cumplimiento de las normas vigentes que eximen a los indígenas de prestar el servicio militar obligatorio como garantía de la integridad social y cultural, y la exoneración del pago de la tasa de compensación militar.

ARTICULO 16. CONSULTA Y CONCERTACION. En los procesos de consulta y concertación de cualquier medida legislativa o administrativa susceptible de afectar a comunidades o pueblos indígenas determinados, podrán participar los indígenas integrantes de la Mesa Permanente de Concertación o sus delegados. Los procedimientos que se prevean realizar les serán informados con la suficiente antelación.

ARTICULO 17. El funcionamiento de la Comisión Nacional de Territorios Indígenas y de la Mesa Permanente de Concertación con los Pueblos y Organizaciones Indígenas se regirá por las siguientes reglas:

1. Podrán deliberar con la asistencia comprobada de la mitad más uno de los miembros indígenas, el Viceministro de Desarrollo Rural Campesino del Ministerio de Agricultura y Desarrollo Rural o el Ministro del Interior o sus delegados, según el caso, y los miembros de las entidades competentes de los temas a tratar.

2. Las decisiones se adoptarán por consenso.

3. Las reuniones ordinarias de la Comisión Nacional de Territorios Indígenas se harán por lo menos dos veces cada mes durante los primeros cuatro meses mientras se cumplen las funciones a que se refiere el parágrafo 2o. del artículo 2o. del presente Decreto y, posteriormente según lo determine el reglamento. El Viceministro de Desarrollo Rural Campesino será responsable de las convocatorias.

4. Las reuniones ordinarias de la Mesa Permanente de Concertación con los Pueblos y Organizaciones Indígenas se harán por lo menos una vez cada mes durante el año de 1996, y posteriormente según lo determine el reglamento. El Ministro del Interior será responsable de las convocatorias.

5. Sesionarán en la ciudad de Santafé de Bogotá D.C., pero podrán realizar reuniones ordinarias o extraordinarias en cualquier lugar del país.

6. Serán dotadas por las entidades estatales que las conforman, de recursos suficientes para su funcionamiento y el cumplimiento de sus funciones y para el desplazamiento y manutención de los miembros indígenas que residen fuera de Santafé de Bogotá, en la medida en que dicho desplazamiento no pueda costearse con recursos provenientes de otros fondos públicos.

ARTICULO 18. La Comisión de Territorios Indígenas y la Mesa de Concertación [illegible] conformada por tres (3) miembros

y Desarrollo Rural o el Ministro del Interior, quienes las coordinarán; uno por las otras entidades gubernamentales que la conforman y uno por los miembros indígenas, respectivamente.

La secretaría operativa cumplirá las siguientes funciones:

a) Preparar las reuniones ordinarias y extraordinarias del organismo de que se trate

b) Recoger y organizar la información que será sometida a la consideración del organismo respectivo

c) Elaborar las actas de las reuniones;

d) Impulsar la ejecución de las decisiones, y

e) Las demás funciones que les asignen el reglamento o los organismos respectivos

ARTICULO 19. El Gobierno estimará los costos de funcionamiento de la Comisión de Territorios y de la Mesa de Concertación con el fin de incluir en cada proyecto de Ley de Presupuesto General de la Nación las partidas correspondientes de acuerdo con las normas vigentes. El Gobierno gestionará en el Congreso de la República su inclusión en el Proyecto de Ley de Presupuesto, vigencia fiscal de 1997.

ARTICULO 20. La selección de los miembros indígenas de las Macrorregiones para el período 1996, se hará de común acuerdo por los demás miembros indígenas de cada organismo. A partir de 1997 tendrán un período de dos años y el Gobierno financiará los gastos que demanden las reuniones de las organizaciones por macrorregión, requeridas para su selección, previa concertación de los presupuestos en la Mesa de Concertación.

ARTICULO 21. La Comisión Nacional de Territorios Indígenas y la Mesa Permanente de Concertación, serán instaladas por el Viceministro de Desarrollo Rural del Ministerio de Agricultura y Desarrollo Rural y por el Ministro del Interior, respectivamente, en el término de treinta (30) días contados a partir de la fecha de expedición del presente Decreto.

ARTICULO 22. VIGENCIA. El presente decreto rige a partir de su publicación.

PUBLIQUESE Y CUMPLASE
Dado en Santafé de Bogotá, D.C. a los - 8 AGO. 1996

HORACIO SERPA URIBE

JOSE ANTONIO OCAMPO GAVIRIA
Ministro de Hacienda y Crédito Público

LUZ AMPARO FONSECA PRADA
Viceministra de Desarrollo Rural Campesino
Encargada de las Funciones del Despacho de la
Ministra de Agricultura y Desarrollo Rural

JOSE VICENTE MOGOLLON
Ministro del Medio Ambiente

RODRIGO MARIN BERNAL
Ministro de Desarrollo Económico

OLGA DUQUE DE OSPINA
Ministra de Educación Nacional

MARIA TERESA FORERO DE SAADE
Minjstra de Salud

MILJØMINISTERIET

MINISTRY OF THE ENVIRONMENT

DANISH FOREST AND NATURE AGENCY

Convention on Biological Diversity
Secretariat

29. April 2003

Notification SCBD/SEL/VN/34378 – implementation of decision VI/24 on access and benefit sharing. The role of intellectual property rights in the implementation of access and benefit sharing arrangements.

In the above notification of 9 April 2003 the Secretariat has requested information regarding *inter alia* the role of intellectual property rights in the implementation of access and benefit sharing arrangements.

Denmark in 2000 has enacted a "disclosure of origin clause" in its IPR legislation. Below are some data about the clause:

Act 412, 31/5 2000 amended the Danish Patent Act (consolidated Patent Act 926/22/9 200) in order *inter alia* to implement the EU Directive on biotechnological inventions. Based on the Act, the existing ministerial regulation on patents (Reg. 374 19/6 1998) was amended (reg. 1086 11/12 2000) by supplementing its para 3 with the following provision (unofficially translated):

"If an invention concerns or makes use of biological material of vegetable or animal origin, the patent application shall include information on the geographical origin of the material, if known. If the applicant does not know the geographical origin of the material, this shall be indicated in the application. Lack of information on the geographical origin of the material or on the ignorance hereon does not affect the assessment of the patent application or the validity of the rights resulting from the granted patent".

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Breach of this provision could imply a violation of the obligation in the Danish Penal Code (para 163) to provide correct information to a public authority.

Yours sincerely,

Christian Prip

-----Original Message-----
From: esid [mailto:esid@telceom.net.et]
Sent: 17 January, 2003 1:16 AM
To: secretariat@biodiv.org
Subject: SUBMISSION OF VIEWS ON THE BONN GUIDELINES

Dr. Hamdallah Zedan

Executive Secretary

Convention on Biological Diversity

Fax: 514-288-85 88

Montreal, Canada

Dear Zedan,

Subject: SUBMISSION OF VIEWS ON THE BONN GUIDELINES

Thank you very much for providing us with the opportunity to express our views on the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of Their Utilization.

We commend the Secretariat for the excellent work that it has done in producing this immensely important document. The comments provided under the document provided herein below are essentially of a general nature. We trust that we will, with the continued support of the Secretariat, have the opportunity to air our views regarding details and editorial matters in the second meeting of the Ad-hoc Open Ended Working Group Meeting on ABS.

Yours truly,

Dessalegne Mesfin

9/16/2003

COMMENTS ON THE BONN GUIDELINES

I. GENERAL

a. In principle guidelines are meant to facilitate/expedite compliance with the provisions of a legally binding instrument. It also helps, among others, filling missing details or overcoming the clarity that the Convention at the moment lacks due to its framework nature. Moreover, the fact that they are voluntary denies them universality or unanimous acceptance by all the Parties is nearly impossible, if not totally impossible.

The only instrument that could have addressed such a draw back is a protocol to the Convention on ABS (in the same way as the Cartagena Protocol is) and this is long overdue. Therefore the process to develop a legally binding regime such as protocol on ABS has to be started. This is all the more relevant for the technologies that put in use genetic resources and associated traditional practices, knowledge and technology etc are protected by a legally binding instrument.

b. According to the Guidelines, the two sides entering a contractual agreement of access are, on the side of providers, strictly a state (through the Competent National Authority) and, on the side of users, not necessarily a state or even a state entity.

This is surely a crying imbalance that needs to be redressed as a state, relatively speaking, is very visible, stable, enduring and with infinite resources at its disposal while this is not so with non-state entities. To overcome this glaring shortcomings and also to build trust among contracting parties and thereby to facilitate the transaction the Guidelines have to provide a mechanism in which the state of which the user is citizen assumes the major responsibility on behalf of or together with the user. This concern needs to come out clear and be addressed in the guidelines accordingly.

c. It would have been good if the Guidelines have tried to address the issue of the retroactive application regarding access and benefit sharing. This issue has to be tabled for negotiation and a concrete final decision should be taken on the matter. This can be done in the course of developing the current guidelines.

d. The foci of the Guidelines are traditional knowledge, innovations and practices. This should have included a fourth element, namely, indigenous and traditional technology in keeping with, say, Article 16 sub article 4 of the Convention. Technology, in the sense of indigenous and traditional, should appear wherever the other three are mentioned in the Guidelines.

e. Terms like 'derivative', 'access', 'Prior Informed Consent', 'provider', 'in situ source', " derivative' and 'user' which subject matters of in the Guidelines need to be defined.

Terms like 'country of origin' and 'country providing genetic resources' need to be elaborated upon.

II. ARTICLE BY ARTICLE COMMENT

a. Annex

i. Write Article 1 sub article 4 to read:

"Nothing in these Guidelines should be interpreted to affect the sovereign rights of States over their natural resources ***and the rights of indigenous and local communities over their technology, knowledge, innovation and practices as provided in the respective national laws;"***

ii. The terms 'provider', 'user' and 'stakeholder', as found and used in Article 1 subatricle 5, are neither defined in the Guidelines nor are they in use under the Convention. Therefore:

1. replace them with their equivalent terms in the Convention; or

2. define them is such a way that that they are in keeping with the spirit of the Convention and enhance/facilitate its objectives.

iii. Replace Article 1 sub article 6 to read:

"Nothing in these Guidelines should be interpreted as affecting the rights and obligations relating to genetic resources arising out of the mutually agreed terms under which the resources were obtained from the country of origin ***and as long as they are in***

conformity with the relevant provisions of the Convention;"

iv. Delete the phrase "are voluntary and" in the chapeau of Article 7 as it is redundant and rewrite sub article 'a' to read:

"The present Guidelines ~~are voluntary and~~ were prepared with a view to ensuring their:

a) Voluntary nature: they are intended to guide both users and providers of genetic resources ~~on a voluntary basis~~ ***'in order to comply with their respective obligations under the Convention'***";

v. The phrase "in situ sources", as it is found in the definition of 'country providing genetic resources' in the Convention (Article 2), is far from clear; unlike the phrases 'in situ conditions', 'in situ conservation', 'ex situ conservation', etc. In the Convention neither is 'situ' defined. Thus, it amounts to denying clarity and definiteness to such an important phrase of the Convention as 'Country providing genetic resources'.

vi. In Article 10, replace the phrase 'international agreements' to read 'international ***environmental*** agreements' and add at the end of sentences 3 and 4 '***as long as they conform to the relevant provisions of the Convention***'.

vii. In Article 11 sub-article 'd', recalling the comments already made regarding terms to be defined, the term 'stakeholder' shall not be construed to mean only 'providers' and 'users' but such actors as states of providers and users.

viii. In Article 11 sub-article 'e', insert the word 'enforcement' after implementation in line 1.

ix. In Article 11 sub-article 'h' replace 'above' in the last line with the word 'herein'.

x. Delete sub-article 'l'. The rationale to single out one item of access and dwell on it in such general part of the Guidelines, as objectives, is not clear.

xi. Part "C" Articles 16 sub-article 'a', add after the word in 'Convention' in the second line of the chapeau the words '***and the terms and conditions of the access permit;***'

xii. Article 16 sub-article a. (iii), add after the words 'genetic resources' in the last sentence '***by indigenous and local peoples in accordance with their practices and customary laws;***'

xiii. Article 16 sub-article a. (v), insert the words '***undertake socio-economic and environmental impact assessment in order to***' after the word 'stakeholders' in line 1.

xiv. Introduce the following new items under Articles 16 sub-article and a(ix), respectively, that read:

a(viii) "Establish mechanisms to ensure that users comply with the obligations emanating from the terms and condition that they have entered into."

a(ix) "Establish mechanisms to redress situations of over- or under-rating of benefits arising from over- or under-valuations of genetic resources, respectively, realized in the course of implementing access agreements;"

xv. Articles 16 sub-article b. (iii), insert the words '***comply with and***' at the beginning of the sub-article before the word 'Respond'.

xvi. Articles 16 sub-article b. (viii), insert the words '***with the prior written consent of the original provider***' in the first line following the comma after the words 'third parties' and at the end of line 5 after the words 'agreed terms'.

xvii. Articles 16 sub-article c. (chapeau), delete the word Providers and replace it with '***Contracting parties providing genetic resources***'.

xviii. Articles 16 sub-article c. (i), insert the words '***after obtaining the consent of the local community or communities through consultation***' at the end of the sentence.

xix. Articles 16 sub-article c. (ii), delete the words 'Strive to' at the beginning of the sentence.

xx. Articles 16 sub-article d (chapeau), delete the words 'with users of genetic resources under their jurisdiction' and in their place insert the words '***which have acquired genetic resources***'.

xxi. Add a new sub as sub-article 7, reading:

"Providing state liability for redressing alleged infringements."

Read the original sub-article 7 as sub 8.

xxii. Part III Article 20 sub-article 'a', insert the words '***evaluation of benefits***' after the words 'scientific' in line 1.'

Article 20 sub-article 'b', delete 'and contractual terms' at the end of the sentence.

EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate E - Global and international affairs
ENV.E.3 - Development and the Environment; Mediterranean

Brussels, 25 February 2003
CB/NN D(2003) 630112

CBD Secretariat
World Trade Center Building
393, Saint Jacques Street, Suite 300
Montreal, Quebec, Canada H2Y 1N9

Subject: CBD Notifications on Access and Benefit Sharing (ABS), 2002/57; Liability, 2003/5.

Please find here enclosed our responses to the above notifications

ABS

The EC has submitted its thematic report on access and benefit-sharing in 2002. This extensive report (now available on the CBD website) contains, in a narrative form, a large amount of information, including examples of benefit-sharing arrangements, which we believe would provide valuable elements in response to notification 2002/57. Moreover, in relation to the issue of Prior Informed Consent, we would like to draw your attention to EC Directive 98/44 already submitted to the Secretariat in previous occasions, which, in paragraph 27 of its preamble, provides for an encouragement to disclose the origin of genetic resources in patent applications (The Directive is available on http://europa.eu.int/servlet/portail/RenderServlet?search=DocNumber&lg=en&nb_docs=25&domain=Legislation&coll=&in_force=NO&an_doc=1998&nu_doc=44&type_doc=Legislation) .

Finally, we would also like to draw your attention to the attached 'Communication on the Review of Article 27.3(b) of the TRIPs Agreement' sent by the EU in September 2002 to the TRIPs Council which deals, inter alia, with the issues of 'disclosure' and traditional knowledge.

Liability

Please find in attachment the CVs of our experts for the liability meeting to be held next June. We would like to propose Dr Nicola Notaro as an expert and Ms Jolanda Villar Ruberte as an observer.

Best regards

"Signed"
Christoph BAIL
Head of Unit

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Office: BU-9 5/175. Telephone: direct line (32-2) 295 40 99. Fax: (32-2) 296 95 57.

E-mail: christoph.bail@cec.eu.int

COMMUNICATION BY THE EUROPEAN COMMUNITIES AND THEIR MEMBER STATES TO THE TRIPS COUNCIL ON THE REVIEW OF ARTICLE 27.3(B) OF THE TRIPS AGREEMENT, AND THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD) AND THE PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE

"A CONCEPT PAPER"

EXECUTIVE SUMMARY

This text addresses the issues dealt with under Paragraph 19 of the Doha Declaration, which instructs the TRIPs Council to continue the review of Article 27.3(b) TRIPs, and to examine the relationship between TRIPs and CBD and the protection of Traditional Knowledge (TK) and folklore, and other relevant new developments. It reflects the EC's stated willingness to commit to this process in a spirit of openness, with the aim of finding ways of interpreting and implementing the TRIPs Agreement in a way to support the objectives of the CBD.

The review of Article 27.3(b)

This review deals, *stricto sensu*, with the patentability of biotechnological inventions and the protection of plant varieties. This subject has an important link with development issues in agriculture, so the development dimension must be fully taken into account.

The European Communities and their Member States (hereinafter "the EC") see no reason to amend Article 27.3(b) as it now stands. The TRIPs Agreement allows members sufficient flexibility to modulate patent protection as a function of their needs, interests or ethical standards. In this connection Article 27.3(b) - in conjunction with Article 27.2 (exclusion from patentability of inventions the commercial exploitation of which is necessary to protect ordre public or morality) and Article 27.1 (patentability criteria) - provides considerable leeway.

The EC have already indicated that they are prepared to discuss certain technical issues related to Article 27.3(b). However, in the EC's view, trying to clarify the definitions of technical terms such as "micro-organism" in the TRIPs Council may not be the best way forward. Firstly, because it would be extremely difficult to agree on precise definitions in that context, and, secondly, because it is questionable whether more precise definitions are really necessary, given that they would reduce the flexibility of WTO Members.

The relationship between the TRIPs Agreement and the CBD

From a legal perspective there is no conflict between the CBD and the TRIPs Agreement. However, it would be wrong to put on end to all discussion by saying that, in the absence of legal incompatibility, there cannot be a problem with the implementation of both Agreements. There is considerable *interaction* between both agreements, so TRIPs and CBD can and should be implemented in a mutually supportive way. The TRIPs Council should focus on ways and means of doing this.

At national level, sound regulation (through legislation or administrative or policy measures) on access and benefit-sharing (ABFS) under the CBD is essential to guarantee legal security for all parties involved and to protect the rights of providers of genetic resources. Further details can be settled through contractual arrangements. Legislation/policy measures and contracts are complementary instruments for ensuring fair implementation of the CBD.

Further synergies between the implementation of these agreements can be worked out at international level by ensuring policy coherence in all forums which deal with issues relevant to the interplay between TRIPs, the CBD and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture. In this respect the Bonn Guidelines on Access to Genetic Resources and Benefit-sharing adopted at the 6th Conference of the Parties in The Hague on 19 April 2002 are an important evolution.

Disclosure of origin

The EC agree to examine and discuss the possible introduction of a system, such as for instance a self-standing disclosure requirement, that would allow Members to keep track, at global level, of all patent applications with regard to genetic resources for which they have granted access. The EC see merit in a system that would ensure transparency and would allow the authorities of countries granting access to their resources to keep track of patent applications linked to the use of these resources.

Under such a system, the information to be provided by patent applicants should be limited to information on the geographic origin of genetic resources or TK used in the invention, while such a disclosure requirement should not act, de facto or de jure, as an additional formal or substantial patentability criterion. Legal consequences to the non-respect of the requirement should lie outside the ambit of patent law.

Protection of TK

Preventive approaches to avoid misappropriation of traditional knowledge and to stimulate the sharing of benefits could be dealt with by the TRIPs Council. We need to explore methods of documenting and sharing information on TK, such as databases and registers, in order to allow patent examiners to take them into account in prior art searches. When TK is used as a basis for further innovations, disclosure of the original TK from which inventions are derived would be an important way of ensuring that holders of traditional knowledge share in the benefits.

The EC support further work towards the development of an international *sui generis* model for legal protection of TK in WIPO. At this stage, the TRIPs Council is not the right place to negotiate a protection regime for a complex new subject matter like TK or folklore. This is an issue where the WTO should ideally be able to build on the work done by the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore. Depending on the outcome of the WIPO process, the TRIPs Council will have to determine whether this result warrants further work in the WTO.

Effective sui generis protection of plant variety rights

The absence of a definition of this concept means that Members have a considerable degree of flexibility in determining how their legislation meets the standard of effectiveness, thus allowing them to design a protection regime that is appropriate to their specific national situation. Although the UPOV Convention meets the standard of effectiveness in Article 27.3(b), other protection models may be equally effective.

This paper explores the criteria that any regime establishing rights over plant varieties must fulfil (for example, a clear definition of the protectable subject matter and the conditions for granting protection, the availability of enforcement procedures, etc.).

Farmers' rights and farmers' exemptions

Farmers' exemptions (*i.e.* exceptions to plant variety rights or patents allowing farmers to save, use, exchange or sell seeds of protected varieties or seeds) can, under certain circumstances, be justified under Article 27.3(b) of the TRIPs Agreement, or under Article 30 of the TRIPs Agreement. The special situation of least developed or developing countries could be addressed by specific exceptions allowing subsistence farmers or small farmers to save, replant, exchange, share and resell seed, provided they do not use the commercial denomination of the variety. Farmers with significant commercial interests should remain subject to more stringent rules.

1. Introduction

1. Paragraph 19 of the Doha Declaration instructs the TRIPs Council to continue the review of Article 27.3(b) of the TRIPs Agreement, and to examine the relationship between the TRIPs Agreement and the Convention on Biological Diversity (hereinafter called CBD) and the protection of Traditional Knowledge (hereinafter called TK) and folklore (as well as other relevant new developments), both in the context of this review and as part of the work arising from paragraph 12 of the Doha Ministerial Declaration (outstanding implementation points) and the review provided for by Article 71.1 of TRIPs. The recent adoption of the FAO International Treaty on Plant genetic Resources for Food and Agriculture and of the Bonn Guidelines on Access to Genetic Resources and Benefit-sharing are important relevant new developments which are also dealt with in this document.

2. In the WTO, the relationship between the TRIPs Agreement and the CBD and the protection of traditional knowledge have so far been dealt with exclusively under the review of Article 27.3(b) of the TRIPs Agreement.

3. The Doha Declaration further specifies that, in undertaking this work, the TRIPs Council is to be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPs Agreement and should take full account of the development dimension.

4. The European Communities and their Member States (hereinafter "the EC") welcome this broad mandate, because the EC have always been of the opinion that review of 27.3(b) was too narrow a basis for dealing with the wide array of complex issues raised by this review. Also, the EC hold the view that both processes, i.e. the review of 27.3(b) and the examination of the relationship between the TRIPs Agreement and the CBD are, by virtue of their numerous interconnections, inextricably linked. This new mandate arising from the Doha Development Agenda (hereinafter "the DDA") means we can now give this debate more attention.

5. The EC have already expressed a first series of views on the relationship between intellectual property, on the one hand, and biodiversity and TK, on the other, in the communication of 3 April 2001. In this document the EC concluded that the search for solutions to the developing countries' concerns, expressed within the context of the review of Article 27.3(b) of TRIPs, does not necessarily lie within the scope of that Article itself, but may rather be found :

- in developing appropriate instruments to achieve the objectives of the CBD (in particular in particular access to genetic resources benefit-sharing and protection of traditional knowledge) and those objectives of the TRIPs Agreement which, in the view of the developing countries, have not been sufficiently promoted by the developed countries (i.e. the protection of TK, or transfer of technology and know-how);

- in providing technical assistance to developing countries to implement the CBD through sound an effective legislative, administrative and policy measures; and

- through the possible negotiation of measures within the IPR system (in particular in the context of WIPO and the TRIPs Agreement) aimed at facilitating benefit sharing and protecting sovereign access rights (e.g. to insert a provision on the disclosure of origin or to develop protection of traditional knowledge.

6. It was therefore concluded that these issues would be better dealt with within the framework of the new round of trade negotiations as part of a comprehensive package. The DDA now provides for this framework.

7. The EC want to engage in this process in the same spirit of openness so as to find ways of interpreting and implementing the TRIPs Agreement so as to support the objectives of the CBD, like for example the fair and equitable sharing of the benefits arising from the use of genetic resources.

8. To achieve this, the EC believe it might be useful for those countries which have a particular interest in these issues and have specific demands to submit a comprehensive presentation of these demands as a basis for structured and fruitful discussion. The EC are looking forward to receiving concrete proposals from Members who have raised specific concerns in the TRIPs Council.

9. The EC are willing to consider proposals which genuinely reflect the concerns of developing countries, provided these do not affect the substance as well as the balance of rights and obligations laid down in the TRIPs Agreement, and maintain the rights of Members to create a favourable intellectual property environment for research in the area of biotechnology.

10. The EC takes this opportunity to draw the Membership's attention to the fact that specific attention is given to the issues under discussion here in their Action Plan on Life Science and Biotechnology. In particular, Action n° 26 of the Plan foresees that "The Commission and the Member States will support the conservation and sustainable use of genetic resources in developing countries and their equitable sharing of benefits arising from their use, inter alia by supporting the development and enforcement of effective measures to conserve, to use sustainably and to provide access to genetic resources and traditional knowledge, as well as to share equitably the benefit arising from them, including income generated by intellectual property protection"[1].

2. The review of Article 27.3(b)

11. This review process, which started in 1999, deals *stricto sensu* with the patentability of inventions, including biological material (biotechnological inventions), the protection of plant varieties and possible exclusions to patentability.

12. At the TRIPs Council meeting on 21 March 2000, the Chairman concluded that the Council should proceed in a more orderly, systematic and productive manner by focusing on :

- the link between Article 27.3(b) and development
- technical issues relating to patent protection under Article 27.3(b)
- technical issues relating to sui generis protection of plant varieties
- ethical issues relating to the patentability of life forms
- the relationship with the conservation and sustainable use of genetic material
- the relationship with the concepts of TK and farmer's rights.

These issues call for certain comments.

Link between Article 27.3(b) and development

13. Now that we are in the context of the DDA, the link between Article 27.3(b) and development should be the central theme of our debate. This is emphasised by paragraph 19 of the Doha Ministerial Declaration, which instructs the TRIPs Council to be guided by Articles 7 and 8 TRIPs and to take the development dimension fully into account.

14. The subject matter of Article 27.3(b) - biotechnological inventions and plant varieties - has an important link with development issues in the agricultural sector. Biotechnology offers enormous potential and can play a role in improving the agricultural output, health and the environment of the developing world. It is a sector where intellectual property protection plays an important role because it often requires a considerable amount of high-risk investment.

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[1] Also, the European Commission financed or co-financed several seminars and workshops on related issues such as :
- The Role of Intellectual Property Protection in the Field of Biodiversity and Traditional Knowledge (Brazil, 2001, co-organised with the Brazilian Institute of Intellectual Property)
- Developing Global Bioresources (London 2002)
- Microbial Biodiversity and Biotechnological Opportunities in the Humid Tropics (Venezuela, 2002)

When determining how to implement Article 27.3(b), it is crucial to assess its impact on the possible development of biotech research.

15. At the same time, it is true that access by the developing world to these important technologies, as well as their capacity to deal with the potential risks associated with these technologies, remains limited. Agricultural technologies, and biotechnology in particular, are therefore an important issue to be tackled in the context of transfer of technology and capacity-building.

Technical issues relating to patent protection under Article 27.3(b)

16. The EC have already indicated that they are prepared to discuss certain technical issues related to Article 27.3(b) (such as for example domestic implementation of Article 27.3(b), issues related to the patentability of inventions including biological material and the protection of plant varieties, possible exclusions to patentability, etc.).

17. Some WTO Members have requested that the TRIPs Council examine and clarify the definition of certain terms used in Article 27.3(b), e.g. "microbiological processes", "essentially biological processes" or "micro-organisms", in order to make it clearer what can and what cannot be excluded from patentability under Article 27.3(b).

18. In this regard, the EC takes the view that those Members advocating more precise *definitions* of the technical terms used in Article 27.3(b) should be aware of the difficulties of getting all WTO Members to agree on definitions. It is indeed questionable whether the TRIPs Agreement could or should go into this amount of detail.

19. And it will not be easy to get the TRIPs Council to agree on clarification of these terms, because decisions are made by consensus and the issues are complex. The EC are therefore of the opinion that the TRIPs Council is not the right forum to agree on *definitions* of technical terms. This could rather be examined in the context of WIPO, which has more expertise on these specific technical issues.

20. Another argument against clarification in the context of the TRIPs Agreement is that the absence of definitions of certain terms gives an element of flexibility, leaving Members some freedom to interpret terms broadly or strictly within reasonable limits.

21. An example of a term that is not defined in TRIPs is the term "micro-organisms". There is also no commonly accepted definition of "micro-organism" in science, international conventions or patent office practices. Nevertheless, the definition of its scope at domestic level is important, as micro-organisms are widely used in the pharmaceutical, chemical or biotech industries and they are the only form of living organism for which WTO Members are obliged to provide patent protection. However, the patentability of micro-organisms depends on whether or not the patentability criteria are met, thus rendering the definition issue less important. As stated, other international conventions fail to provide a definition, e.g. the 1977

Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure.

22. Also there are divergent views among scientists as to what the term "micro-organism" encompasses. But there is some agreement as to its core meaning: "micro-organism" is generally understood to refer to living beings other than plants and animals, i.e. bacteria, fungi, viruses, etc. The *Concise Oxford Dictionary of Current English* (which has been used by WTO panels for interpretation purposes) defines "micro-organism" as an organism not visible to the naked eye, e.g. bacterium or virus. Taking into account the rules of Treaty interpretation, as set out in the Vienna Convention of the Law of the Treaties, and although this is no more than a first step in this process, this definition of the Oxford Dictionary can be considered as providing a standard of reasonableness within which Members can modulate the definition. In this way, WTO Members can determine the scope of what is patentable and what is not.

23. Moreover, microbiology is a fast-moving science, which has led classifications such as "micro-organism" to evolve rapidly. This also raises the question as to whether a more precise definition is really necessary, since it would reduce the flexibility of WTO Members while introducing new uncertainties, given the rapid evolution of knowledge, technologies and applications in the field of microbiology

24. Finally, the task of "review" does not mean that WTO Members are under a duty to agree on an exhaustive definition of each and every term. But rather to see how different Members do for themselves define and apply these terms.

Technical issues relating to sui generis protection of plant varieties

25. The effective protection of plants is an important issue and will be dealt with in Section 5.

26. The review of Article 27.3(b) could be used to clarify the potential benefits and limitations of different national and international schemes for the protection of plant varieties.

Ethical issues relating to the patentability of life-forms

27. The EC acknowledge that issues relating to the patentability of life forms need to be addressed carefully. Different societal values come into play. In fact the TRIPs Agreement does allow Members to take these considerations into account. Article 27.3(b), in conjunction with Article 27.2 (exclusion from patentability of inventions the commercial exploitation of which is necessary to protect ordre public or morality) and Article 27.1 (patentability criteria), already allow Members considerable freedom to modulate the patentability of biotechnological inventions. For instance, the interpretation of the patentability criteria under Article 27.1 may slightly differ from Member to Member, which may lead to certain nuances in approach when distinguishing between an invention and a discovery. This is evidenced by disparities in the legislation and practices of developed countries. It is up to each country to strike the right balance, taking into account economic, ethical and other concerns,

without losing sight of the fact that granting intellectual property rights to biotech inventions is one of the key factors for developing domestic skills in this sector.

28. It should be remembered that Article 27.3(b) is the result of a carefully negotiated balance: calls to reopen 27.3(b) in order to change that balance may give rise to counterclaims by other Members to make it compulsory to patent broader categories of biotech inventions, including plants and animals. The EC are in favour of maintaining the current balance of the TRIPs Agreement, which gives WTO Members a large degree of flexibility with regard to patentability of biotech inventions, and therefore see no reason to amend Article 27.3(b) as it now stands.

29. The EC established the scope for the legal protection of biotechnological inventions in Europe in Directive 98/44 of the European Parliament and of the Council on the legal protection of biotechnological inventions. It authorises EC Member States to exclude biotech inventions from patentability where their commercial exploitation conflicts with "ordre public" and morality, and includes an illustrative list of inventions excluded from patentability, such as interventions in the human germline, cloning of human beings and the processes referred to or the use of human embryos for industrial or commercial purposes. The EC invites other Members to adopt a similar approach. The EC would welcome further information about the experience of other Members in patenting biotech inventions and dealing with the related ethical aspects.

The relationship with the conservation and sustainable use of genetic material

30. This issue refers to the broad relationship between the TRIPs Agreement and the CBD. Strictly, this issue does not fall within the direct scope of Article 27.3(b), but appropriate solutions will be discussed in the section on TRIPs and CBD below.

The relationship with the concepts of traditional knowledge (TK) and farmers' rights

31. TK is in the EC's view an issue that, strictly speaking, does not fall exclusively within the scope of Article 27.3(b). As a matter of fact, protection of TK is relevant to several other Articles of the TRIPs Agreement which deal with patents, e.g. Articles 27.1 and 29. It is more appropriate therefore to deal with it under a separate heading (Section 4).

32. The issues of **farmers' rights** and farmers' exemptions are directly linked with the intellectual property protection of plants and plant varieties, and will be dealt with in Section 6 of this communication.

3. The relationship between the TRIPs Agreement and the CBD

Interface between two mutually supportive instruments

33. In its Articles 16.2 and 16.5 the CBD acknowledges the need to act in consistency with the adequate and effective protection of intellectual property rights and urges Members to ensure that intellectual property rights are supportive to the CBD. The CBD language relating to intellectual property strikes a fine balance

between the need to implement intellectual property protection and the need to ensure that intellectual property rights facilitate conservation and sustainable use of biodiversity and the ABSF principles. It is a fact that the TRIPs Agreement, in its turn, does *not* refer to the principles of the CBD as regards access to genetic resources and the sharing of the benefits arising from their use. This does not mean, however, that the TRIPs Agreement runs counter to the CBD! There is nothing in the TRIPs Agreement that would prevent the sharing of the benefits arising from intellectual property protection over inventions incorporating genetic resources or the protection of traditional knowledge. At the same time, it is true that the TRIPs Agreement does not provide for direct tools to establish a link between intellectual property protection and compliance with the principles of the CBD.

34. As regards the relationship between the TRIPs Agreement and the CBD, the EC's April 2001 Communication was based upon two basic premises.

35. First, the CBD and the TRIPs Agreement do not conflict with each other from a legal perspective. They have different objectives and do not deal with the same subject matter. There is nothing in the provisions of either Agreement that would prevent a country from fulfilling its obligations under both. The CBD, for example, does not prohibit patents on inventions using genetic material. TRIPs does not prevent signatories to the CBD from exercising their right to regulate access to their genetic resources, to require prior informed consent or to share in the benefits arising from their use.

36. Second, closing the door to any debate on the grounds that, in the absence of legal incompatibility between the two Agreements, there cannot be a problem with the implementation of both Agreements would not be the right attitude. Despite their difference in coverage, there is indeed considerable *interaction* between the rights referred to in the TRIPs Agreement and the subject matter of the CBD. There are a range of issues for which both Agreements do have implications such as biotechnology, plant varieties, environmental technology relating to conservation and sustainable use, information relating to conservation and sustainable use, traditional knowledge and benefit-sharing.

37. This leads the EC to the view that, with regard to their implementation, the TRIPs Agreement and the CBD should not undermine each other's objectives. They should, accordingly, be implemented in a mutually supportive way.

38. In its implementation, the TRIPs Agreement can in fact be used to support the objectives of the CBD, such as the fair and equitable sharing of the benefits arising from the use of genetic resources. Intellectual property can be a suitable instrument for implementing the CBD. Intellectual property rights can encourage the use of genetic resources by promoting biotechnological innovation. Intellectual property rights generate financial benefits further to commercial exploitation. So, provided that international law (and in particular the CBD), national legislation and contractual arrangements on access and benefit-sharing are fully respected, there is scope for congruence of interests between providers and users, through the use of intellectual property rights, given that the latter contribute to creating benefits stemming from the use of genetic resources in the form of financial returns or access to the relevant technology.

39. Any examination of the link between the CBD and the TRIPs Agreement should, therefore, focus on ways and means of implementing both instruments in a mutually supportive way and on how to create an interface between the two Agreements.

Ways and means of ensuring mutually supportive implementation of both Agreements

40. The first way is at **national level**. It is the duty of the WTO Members and the CBD signatories to honour their commitments under both Agreements at national level. Both Agreements allow for a significant degree of flexibility with regard to their implementation at national level, thus leaving scope for a balance in the way they are applied. These national implementation measures are the primary instruments for ensuring mutually supportive implementation.

41. The CBD must be implemented at national level by establishing the core conditions for access to national genetic resources and determining minimum conditions for benefit-sharing. This implementation may be by legislative, policy and/or administrative measures. Sound regulation is essential to guarantee legal certainty for all parties involved and to protect the rights of providers of genetic resources. The details of each deal can be set out in the contractual arrangements (material transfer agreements) according to "mutually agreed terms".

42. It is important in this context that those Members, which are the most advanced in domestic policy-making with regard to access and benefit-sharing share their experience with other Members of the TRIPs Council.

43. Further synergies between the implementation of both Agreements can also be created at **international level**. First of all, it is important for governments to ensure policy coherence in all forums dealing with issues relevant to the interplay between TRIPs and CBD in order to ensure an integrated approach across institutions (CBD, WTO, WIPO, FAO ...). In this context, the granting of observer status to the CBD in the TRIPs Council would play a positive role in creating a clearer appreciation of the links between TRIPs and CBD. The direct relationship of the work of the CBD and that of the TRIPs Council, as expressed in Paragraph 19 of the Doha Ministerial Declaration, makes this observership indispensable.

44. It is also important to underline that legislative, administrative and policy approaches on the one hand and contractual approaches on the other hand should not be set against one another. Multilateral rules, national regulatory or policy measures and contractual arrangements are complementary instruments in securing the principles of the CBD. In this regard, the EC welcome the Bonn Guidelines on Access to Genetic Resources and Benefit-sharing adopted at the 6th Conference of the Parties in The Hague on 19 April 2002 which sets out practical ways and means of implementing the principles of prior informed consent and mutually agreed terms enshrined in Article 15 of the CBD at national level. The Bonn guidelines provide useful elements for Material Transfer Agreements and examples of monetary and non-monetary benefits which could be shared. They are accompanied by a set of recommendations on the role of intellectual property rights in the implementation of

access and benefit-sharing arrangements. Their implementation will help to achieve the objectives of access and benefit-sharing and ensure mutually supportive interplay between these principles and intellectual property protection. All stakeholders, governments, scientific and research institutes, companies and indigenous and local communities are invited to implement them.

Disclosure requirements

TRIPs and disclosure of origin

45. A number of Members have expressed the view that the TRIPs Agreement should be amended in order to reconcile or harmonise the Agreement with the CBD (most recently in IP/C/W/356 of 24 June 2002). These proposals are designed to create a direct interface between the Agreements in the TRIPs Agreement itself by incorporating a requirement into the TRIPs Agreement that patent applicants should disclose the geographical source and origin of the genetic material and the related traditional knowledge used, and produce an official certificate or evidence that domestic laws on access and benefit-sharing of the source country have been respected (evidence of prior informed consent and of fair and equitable benefit-sharing).

46. The TRIPs Agreement does not specifically deal with the disclosure of genetic resources used in an invention. However, Article 29 of the TRIPs Agreement requires that the disclosure of an invention must be in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. This means that, where inventions related to genetic resources are concerned, relevant information must be provided as regards the genetic resource concerned. In certain cases, the geographical origin may be one of the relevant elements of information to be provided to allow "a person skilled in the art" to put the invention into practice, in which case patent applicants are obliged to provide this information. Where the disclosure of that information is not essential to put the invention into practice, there is no such obligation.

47. However, the objective of Article 29.1 (*i.e.* disclosure in order to allow reproduction of the invention) is different from the disclosure requirement for genetic resources as proposed by certain WTO Members in the context of the discussion on the relationship between the TRIPs Agreement and the CBD (*i.e.* to facilitate the enforcement of access and benefit sharing requirements) . In most cases, Article 29.1 will *not* require patent applicants to disclose the geographical origin because other elements of information, and/or the deposit of the biological material concerned (as regulated under the Budapest Treaty) would be sufficient to meet the requirements of Article 29.1.

48. In any event, the TRIPs Agreement does not prevent Members from requiring the disclosure of origin in cases where this information is not essential in the meaning of Article 29 TRIPs, or the production of evidence of respect of access and benefit-sharing rules to patent applicants, as long as this requirement does not constitute a patentability criterion and has no bearing on the patentability of the invention or the validity of the patent. Substantive patentability criteria are set out in Article 27.1 of the TRIPs Agreement, while Article 29 lays down obligations that can or must be

imposed on the patent-holder in order to check whether the patentability criteria are met. Compatibility with TRIPs depends on the consequences arising from non-compliance. Thus, the concept of making the patentability of an invention subject to the respect of a requirement to disclose the geographical origin of genetic resources used in the invention (in cases where this information is not required under Article 29.1 TRIPs) or of a requirement to provide evidence of the access and benefit sharing rules constitutes a clear step beyond the current provisions of the TRIPs Agreement.

Self-standing disclosure requirements

49. The EC explicitly recognise disclosure of origin of as a principle in the preamble to Directive 98/44 of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions, although without making it a binding requirement[2].

50. Of course, no WTO Member is obliged under TRIPs to require or encourage patent applicants to disclose the origin of genetic resources or related traditional knowledge used in an invention where this is not required under Article 29, *i.e.* a "self-standing requirement" to disclose the geographical origin of genetic resources for *all* inventions incorporating or based upon such resources. However, because benefits arising from the use of genetic resources are perceived to be generated mainly through the commercial exploitation of inventions derived from biotechnology on the markets of industrialised countries, the interests of those advocating any such requirement are that it should be applied on a world-wide basis. Therefore, the EC acknowledge that it would be more significant if a self-standing requirement were to apply globally rather than only in developing countries.

51. The EC, therefore, agree to examine the possible introduction a system, such as for instance a self-standing disclosure requirement, that would allow Members to keep track, at global level, of all patent applications with regard to genetic resources for which they have granted access.

52. However, the question is how to calibrate such a self-standing disclosure system, especially as regards 1) **the type of information to be submitted by the applicants** and as regards 2) **the legal consequence of failure to disclose**.

53. The EC sees merits in a system that would ensure transparency and would allow the authorities of countries granting access to their resources to keep track of patent applications linked to the use of these resources.

54. Therefore, it is the EC's view that the **information to be provided** by patent applicants should be limited to information on the **geographic origin** of genetic resources or TK used in the invention which they know, or have reason to know. It may indeed happen that a patent applicant is not aware of the country of origin of a genetic resource because it has transited through other countries, research centres, botanical gardens or other ex situ collections. So, when the country of origin is not

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[2] Paragraph 27 of the preamble, stipulates that "*patent applications should, where appropriate, include information on the geographical origin of biological material of plant or animal origin, if known ... this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents*".

known, the patent applicant's obligation would be to indicate the research centre, gene bank or entity from which they acquired the resource, it being understood that the disclosure requirement should not act retro-actively. Practical problems that may arise in this respect should not be overlooked, but duly anticipated and taken into account. Moreover, one should not require further evidence with regard to compliance with access and benefit sharing regulations, especially where many countries in the world do not yet dispose of legislation on access to genetic resources and are not in a position to deliver certificates of evidence[3]. Also, one must take into account that requiring patent offices to check compliance with ABFS requirements may well be a very complicated system to manage.

55. Moreover, the EC hold the opinion that such **a disclosure requirement should not act, de facto or de jure, as an additional formal or substantial patentability criterion**[4]. Failure to disclose, or the submission of false information should not stand in the way of the grant of the patent and should have no effect on the validity of the patent, once it is granted. Legal consequences to the non-respect of the requirement should lie outside the ambit of patent law, such as for example in civil law (claim for compensation) or in administrative law (fee for refusal to submit information to the authorities or for submitting wrong information). Patent law should not be used to sanction non-respect of domestic access and benefit-sharing requirements through the rejection of the patent application or the invalidation of the patent.

56. Thus, the EC are prepared to enter within the TRIPs Council, into discussions on the introduction of a multilateral system for disclosing and sharing information about the geographical origin of biological material used in all patent applications. However, such a system should have no bearing on the patentability of the inventions concerned or on the validity of these patents, and should not place an unreasonable burden upon patent offices and patent applicants. Requirements of patent applicants would involve the indication of the geographical origin of genetic resources, which they know, or have reason to know, or, when the country of origin is not known, the research centre, gene bank or entity from which they acquired the resource.

57. Such a system would meet the concerns expressed by a number of WTO Members because :

> (1) It would help to prevent misappropriation of genetic resources and related traditional knowledge, *i.e.* by allowing patent offices to establish novelty more accurately by making more focused searches;

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[3] In this context, the Cancun Declaration, adopted on 18.02.2002, in view of the 6th session of the Conference of the Parties to the CBD, by the Like-Minded Megadiverse Countries (Brazil, China, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Mexico, Peru, South Africa and Venezuela) declared that they would seek the creation of an international regime which should contemplate in particular "certification of legal provenance of the biological material, prior informed consent and mutually agreed terms for the transfer of genetic material, as requirements to the application and granting of patents, strictly in accordance with the conditions of access agreed by the countries of origin."

[4] Except in those cases where the disclosure of the geographical origin of the genetic resource is already required under Article 29 TRIPs

(2) It would help countries providing access to genetic resources to monitor and keep track of compliance with access and benefit-sharing rules as well as with the contractual arrangements between providers and users of genetic resources. It would allow source countries to be informed, through foreign patent offices, of patent applications incorporating genetic resources or traditional knowledge to which those countries, or their local communities, have granted access. This would enable them to check whether patent applicants have respected national rules on access and benefit-sharing and to detect any commercial benefits from the use of genetic resources, thus making sure that source countries get their share of the benefits, by enforcement if necessary.

58. The EC take the view that problems relating to the fact that genetic material originates from more than one country should be resolved through arrangements among the source countries concerned and/or in the context of the CBD.

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (IT)

59. The relationship between the TRIPs Agreement and the IT has not yet been discussed in detail, due to its recent adoption. The adoption of the IT is an important relevant new development regarding issues related to the patentability of living material. It raises several issues that run in parallel to those raised under TRIPs/CBD.

60. Its provisions regarding IPRs on plant genetic resources covered by a multilateral system call for mutually supportive interpretation of the IT with the TRIPs Agreement and the CBD. As the objectives of the IT will be attained through its close links with the CBD, the conditions for the relationship between the TRIPs Agreement and the IT are similar to the one between the TRIPs Agreement and the CBD. In its Articles 12.3(f) and 13.2.b(iii) the IT acknowledges that access to genetic resources shall be consistent with the adequate and effective protection of intellectual property rights and relevant international agreements. Comparable ways and means to ensure a mutually supportive implementation, as outlined under point 3, will be sought for the IT in its relation to the TRIPs Agreement and the CBD. Currently, a dialogue on the conditions for ABFS is taking place in the context of the IT with an aim to agree on a standard Material Transfer Agreement.

4. Protection of traditional knowledge (TK) and Folklore

61. As regards the protection of TK and folklore, the EC are actively and constructively participating in the various forums where this issue is being discussed, and in particular the CBD, WIPO and the FAO (IT). The present Communication focuses primarily on traditional knowledge. In this respect, the EC refer to the document entitled "Traditional Knowledge and Intellectual Property Rights" submitted by the EC to the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore on 14 June 2002 (WIPO/GRTKF/IC/3/16).

62. There exist three complementary intellectual property approaches to TK:

1. Protection of TK through existing intellectual property rights;
2. Instruments to prevent inappropriate patenting or other types of misappropriation of traditional knowledge and to ensure that benefits stemming from inventions based on TK are properly shared with the providers of that knowledge; and
3. The development of *sui generis* protection.

Protection of TK through existing intellectual property rights

63. Even if it appears difficult to protect all types of TK under existing IP regimes, it may be possible, to a certain extent, to protect certain types of TK or, at least, the way in which it is presented, or products incorporating TK, through existing IP regimes. A number of existing IP standards may potentially be used to this end. This use can take various forms. For more details, see pages 2-3 of WIPO/GRTKF/IC/3/16.

Approaches to prevent inappropriate patenting of TK and to facilitate benefit sharing

64. In many cases, TK is not eligible for patent protection, because it does not, respond to the substantive patentability criteria enshrined in Article 27.1 of the TRIPs Agreement. Some cases have been reported of parties obtaining patent protection merely for copying TK. This amounts to misappropriation of TK and the patent can be challenged for not meeting the patentability criteria. However, it is always preferable to deal with problems before they arise. Also, it must be taken into account that most TK holders do not have the means to engage in litigation that may be costly and time-consuming. Therefore, preventive approaches need to be devised.

65. An effective way of avoiding such practices would be to make sure that TK would always be duly recognised as prior art. Therefore, methods of documenting and sharing information on TK, such as databases and registers, in order to allow patent examiners to take them into account in prior art searches need to be explored. Such databases and registers should be developed with the full participation of the TK holders.

66. The situation is different when TK is used as a basis for further innovations. In many cases, TK serves as a basis or an element in further research and development for use in broader applications. In such cases these innovations are patentable, provided they meet the substantive patentability criteria. But the possibility of obtaining a patent does not override existing legal or contractual requirements to reward TK holders for the use of their knowledge or share the benefits of its use. In this instance, disclosure of origin of TK from which inventions are derived would be an issue. What has been said in this communication as regards disclosure requirements of genetic material also applies, *mutatis mutandis*, to traditional knowledge.

Sui generis protection of TK

67. In their Communication to the TRIPs Council of April 2001 on the relationship between the TRIPs Agreement and the CBD,[5] the EC expressed support for the development of an international model for the legal protection of TK. In this context, the EU also confirmed that it remained open to developing countries' requests to include TK on the agenda of a new round, as the EU had already committed itself to at the Seattle Ministerial in December 1999. This is why the EC welcome the reference to TK in paragraph 19 of the Doha Ministerial Declaration.

68. Certain WTO Members have suggested in the past that they would like to see provisions on TK protection included in the TRIPs Agreement.

69. However, the EC are of the opinion that, at this stage, the TRIPs Council is not the right place to negotiate a protection regime for a complex new subject matter like TK or folklore. This is an issue where the WTO should ideally be able to build on the work undertaken by the World Intellectual Property Organisation (WIPO), where traditional knowledge is now being extensively discussed in the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore.

70. At this stage it is difficult to anticipate the result of the work of the WIPO Intergovernmental Committee. Nevertheless, it is clear from the EU's perspective that WIPO, as the specialised UN agency responsible for the promotion of IP world-wide, is, from a technical viewpoint, the most suitable forum for tackling the issue of legal protection of TK. There are many complex conceptual and operational problems involved in recognising (collective) rights over TK, and there could well be considerable hurdles to overcome when establishing stringent criteria such as the definition of TK as protectable subject matter, the determination of ownership, the modalities of ownership and the scope of rights related to TK. Folklore is being examined independently from TK in the framework of the WIPO Intergovernmental Committee. Attempts to protect expressions of folklore via intellectual property face similar, if not greater, challenges.

71. Therefore, it seems best to wait for the results of the WIPO Intergovernmental Committee and only then decide whether this warrants further work in the WTO. Depending on the outcome of the WIPO process, it could then be assessed whether the issue need to be taken up by the TRIPs Council. For example, it can be considered how and whether a protection regime for TK could ultimately be made enforceable, for instance through inclusion in the TRIPs Agreement. A separate assessment on the possibility of protecting expressions of folklore could only be made in the light of the outcome of the intergovernmental Committee.

5. Sui generis protection of plant variety rights

72. The penultimate sentence of Article 27.3(b) TRIPs states that: "*Members shall provide for the protection of plant varieties either by patents or by an effective* sui generis *system or by any combination thereof*". The Agreement gives no further

[5] IP/C/W/254 (13 June 2001).

guidance of what is to be understood by "*an effective sui generis system*" and there is no agreed interpretation of this term among WTO Members.

73. The absence of a definition means that Members have a considerable degree of flexibility to determine how their legislation should meet the standard of effectiveness, which allows them to design a protection regime that is appropriate to their specific national situation. Account can be taken, for instance, of the overall agricultural development policy objectives of Members or the need to protect certain rights of small farmers or subsistence farmers (see Section 6).

74. Many countries have enacted specific laws granting exclusive rights to breeders of new varieties of plants so that they can receive a reasonable return on past investments. These rights also provide an incentive for continued or increased investment in the future, and confirm the moral right of the innovator to be recognised as such and his economic right to be remunerated for his effort.

75. A growing number of WTO Members have signed the UPOV Convention of 1978 or of 1991. The Convention requires its signatories to provide protection for new varieties of plants and contains explicit and detailed rules on the conditions and arrangements for granting protection. A plant variety is protected if it is distinct, stable, sufficiently uniform and novel. The Convention also contains rules on the scope of protection, possible restrictions and exceptions, and how protection may be forfeited. The UPOV Convention is an effective, flexible and widely recognised protection model for plant varieties, subscribed by 50 states all over the world. It offers many advantages for its signatories. For instance, it establishes, subject to certain limitations, the principle of national treatment for plant-breeders from other Member States and introduces a right of priority.

76. However, while UPOV 1978 and UPOV 1991 should be considered as meeting the standard of effectiveness under Article 27.3(b) of the TRIPs Agreement, they are not necessarily the only valid "effective sui generis systems" for plant variety protection. Other models may exist. Several countries have adopted or are preparing to adopt plant variety protection systems which differ to a lesser or a greater extent from UPOV.

77. In this context, the EC believe that in order to be effective any regime establishing intellectual property rights over a certain subject matter, be it inventions or plant varieties, must fulfil a certain number of criteria. The main criteria are the following :

- the protectable subject matter (i.e. plant variety) must be clearly defined;
- the conditions for granting protection must be clearly defined. In the context of plant varieties, novelty is an essential condition for protection;
- the rights with respect to the protected subject matter need to be clearly spelled out; the right-holder should at least be able to prevent third parties from carrying out certain acts in relation to the protected subject matter over a certain period of time;
- the law must provide for national treatment and most favoured nation treatment; it is logical that Articles 3 and 4 of the TRIPs Agreement apply to plant variety protection as well;

- the procedure to be followed by the breeder to obtain these rights should be spelled out in a detailed and transparent way;
- the necessary administrative organisation needs to be set up to ensure that these rights can be effectively obtained within a reasonable time frame;
- limitations and exceptions to the rights of the right-holder need to be clearly defined; typical examples of such exceptions are experimental use, the right to use a protected variety for further breeding, compulsory licences (in which case Article 31 TRIPs provides a useful yardstick) and certain exceptions to the benefit of farmers (see Section 6 of this paper on farmers' rights and farmers exemptions);
- the period of application of the rights must be determined, but should be sufficient to allow breeders to recover costs and invest in new research;
- the law must provide for legal and institutional implementation procedures to allow the right-holder to enforce his rights and to create an effective deterrent to infringement; the legal actions spelled out in the TRIPs Agreement should be available to the right-holder for this purpose.

6. Farmers' rights and farmers' exemptions

78. The term "farmers' rights" is used to refer to very different concepts. For the sake of clarity it is essential to differentiate between basically two different (though closely interrelated) concepts:

a. "farmers' rights" as a set of measures in recognition of the ancestral role of farmers in developing foodcrop varieties and preserving biodiversity;
b. farmers' rights as an exception to plant breeders' rights or patents, which, in order to avoid confusion with the former concept, we will further refer to as "farmers' exemptions".

Farmers' rights

79. In its broad sense, the term "farmers' rights" refers to a set of measures in recognition of the ancestral role of farmers in developing foodcrop varieties and preserving biodiversity. These might for instance consist of measures to help support farmers in their conservation and development of agricultural biodiversity and plant genetic resources.

80. The term farmers' right has a specific legal meaning under the FAO IT (see its Article 9). Here, farmers' rights are intended to encourage contracting parties to take specific measures to assist farmers in their role as guardians of biodiversity and to ensure that they share in the benefits of further improvements of plant genetic resources (*i.e.* giving priority to a funding strategy to the implementation of agreed plans and programmes for farmers in developing countries protection of agriculture-related traditional knowledge etc.). This provision recognises the importance of farmers' rights, but it is left up to the contracting parties to take measures under their national law. Farmers' rights to save, use, exchange and sell farm-saved seed/propagating material (paragraph 3) are not limited by the Article but are subject to the contracting parties' national laws.

81. In their broad meaning, farmers' rights do not directly interfere with the subject of intellectual property rights, the main aim of which is to encourage innovation. Farmers' rights on the other hand are more a matter of retrospective reward to farming communities for their ancestral role in fostering agricultural biodiversity, which is too broad an aspect to be dealt with by the TRIPs Council. It should rather be dealt with by other organisations, particularly the FAO, although some aspects may be considered in the context of traditional knowledge.

82. In this context, it is important to point out that nothing in the TRIPs Agreement prevents Members from taking measures to encourage, support and reward farmers for their role in the conservation and development of agricultural biodiversity and plant genetic resources.

Farmers' exemptions

83. In a more narrow sense, the term "farmers' rights" is also used to refer to exemptions to plant variety right protection or patents on plants or other genetic material allowing farmers to save, exchange or sell seeds of protected varieties or plants, or use them for further multiplication. Farmers' exemptions are thus a derogation - designed to help the farmer - from the scope of protection conferred by a plant variety certificate or a patent.

84. UPOV 91 provides for a right to restrict breeder's rights. The so-called "farmers' privilege" is a form of farmers' exemption, with a clearly circumscribed scope. It allows (but does not oblige) signatories to grant farmers the right to use, for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting the protected variety on their own holdings.

85. EC Regulation No. 2100/94 on community plant variety rights and EC Regulation No. 98/44 on the legal protection of biotechnological inventions both contain a farmers' privilege clause which applies to the main foodcrops (fodder plants, cereals, potatoes, oil and fibre plants), whereby small farmers do not have to pay any remuneration to the right-holders while other farmers are required to pay an "equitable" remuneration, which must be appreciably lower than the amount charged to licensed farmers. The EC consider that these exceptions are justified under UPOV 91 as well as under Article 30 of the TRIPs Agreement.

86. The EC believe that farmers' exemptions can be justified under Article 27.3(b) of the TRIPs Agreement (as an exception to *plant variety right protection*) or under Article 30 of the TRIPs Agreement (as an exception to *patent protection* on genetic resources for food and agriculture), depending on the scope of the exception.

87. The farmers' privilege under the UPOV Convention (which gives a farmer the right to freely propagate or multiply protected varieties *on his own farm*) is designed for economies where farming has become a commercial and quasi-industrial activity performed by a small minority of the population and where plant breeding has become an industrial plant breeder's activity.

88. This could be different for the least developed or developing countries, where all or part of the farming activity is performed on very small farms at subsistence level or where commercial activities of farmers are of limited geographical scope. In these situations, a Member may well create, in its national law, a broader farmers' exemption for the benefit of subsistence farmers, or of small farmers who customarily reuse seed because they lack access to or financial resources for new seed every growing season. This allows them to save, replant, exchange, share and resell seed (to other small farmers), provided they do not use the denomination of the variety or the related trade mark. In any event, the breeder must remain the only one entitled to derive commercial benefit from the new variety. Another option could be to exempt exchanges of seed that take place within the same community or with neighbours, and between farming communities. However, farmers with significant commercial interests should be subject to more stringent rules.

The EC would be happy to discuss these issues further.

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SECRETARIA DE MEDIO AMBIENTE Y RECURSOS NATURALES

UNIDAD COORDINADORA DE ASUNTOS INTERNACIONALES
Dirección General de Cooperación Internacional

2003. Año del CCL Aniversario del natalicio de Don Miguel Hidalgo y Costilla. Padre de la Patria

36780

MAY 2 7 2003
ACTION HV, VN
FILE
INFO SH, IA, VA, GD, FV, OS

UCAI/2791/03

México, D.F. a 26 de mayo de 2003

SR. HAMDALLAH ZEDAN
SECRETARIO EJECUTIVO
CONVENIO SOBRE DIVERSIDAD BIOLÓGICA
P R E S E N T E

Me permito hacer referencia a su atenta Notificación SCBD/SEL/VN/34378 relacionada con la implementación de la decisión VI/24 sobre acceso y reparto de beneficios y seguimiento de la Reunión Intersesional del Programa de Trabajo Multianual de la Conferencia de las Partes, realizada en marzo pasado.

Al respecto, a continuación me permito transmitir a usted nuestros insumos respecto a los diversos requerimientos sobre el tema de acceso a recursos genéticos y reparto equitativo de beneficios, los cuales se especifican en el siguiente cuadro.

ASUNTO	COMENTARIOS
EL PAPEL DE LOS DERECHOS DE PROPIEDAD INTELECTUAL EN LA IMPLEMENTACIÓN DE LOS ACUERDOS SOBRE ACCESO Y REPARTO DE BENEFICIOS	De los temas que se mencionan en los párrafos 8 y 9 de la citada decisión, consideramos que el más importante para nuestro país es el inciso (c) que se refiere a las medidas, aplicación en la práctica y costos para apoyar el cumplimiento del consentimiento fundamentado previo de la Parte Contratante que proporciona dichos recursos. Sobre este tema, México ha insistido en la necesidad de desarrollar un Certificado de Legal Procedencia (CLP), por medio del cual se asegure el cumplimiento de las condiciones de acceso a recursos genéticos de cada país y minimice los riesgos de apropiación ilegal de los recursos genéticos. El CLP deberá contener información sobre el origen, el consentimiento previo informado del material y el conocimiento, innovaciones y prácticas tradicionales asociadas.

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SECRETARIA DE MEDIO AMBIENTE Y RECURSOS NATURALES

UNIDAD COORDINADORA DE ASUNTOS INTERNACIONALES
Dirección General de Cooperación Internacional

2003. Año del CCL Aniversario del natalicio de Don Miguel Hidalgo y Costilla Padre de la Patria

INFORMACIÓN SOBRE LOS PRINCIPIOS, MECANISMOS LEGALES Y PROCEDIMIENTOS PARA LA OBTENCIÓN DEL CONSENTIMIENTO PREVIO DE LOS INDÍGENAS Y SUS COMUNIDADES BAJO LOS REGÍMENES NACIONALES DE ACCESO A RECURSOS GENÉTICOS.	La regulación del acceso a los recursos genéticos en México con utilización en la biotecnología se encuentra contenida en la Ley General del Equilibrio Ecológico y la Protección al Ambiente (LGEEPA), párrafo 87 bis. Este artículo establece que para el aprovechamiento de los recursos biológicos se requiere de la autorización de la Secretaría de Medio Ambiente y Recursos Naturales, la cual *"sólo se otorgará si se cuenta con el consentimiento previo, expreso e informado, del propietario o legítimo poseedor del predio en el que el recurso biológico se encuentre. Asimismo, dichos propietarios o legítimos poseedores tendrán derechos a una repartición equitativa de los beneficios que se deriven o pueden derivarse de los aprovechamientos a que se refiere este Artículo..."* (SEMARNAT, 1997) Por lo tanto, el párrafo 87bis de la LGEEPA indica que es el propietario o legítimo poseedor del predio en donde se encuentren los recursos genéticos quién podrá dar su consentimiento fundamentado previo. La legislación mexicana no se refiere en particular a comunidades indígenas o locales, ya que el o los propietarios pueden ser o no indígenas. El propietario puede ser un individuo con tierras de propiedad privada, grupos indígenas con tierras de propiedad colectiva o comunidades con tierras ejidales. Actualmente está en discusión una Ley para el Acceso y Aprovechamiento de los Recursos Genéticos, la cual contendrá disposiciones claras y específicas sobre los mecanismos relacionados con el acceso y el reparto de los beneficios.

Agradezco de antemano su amable atención y aprovecho la oportunidad para enviarle un cordial saludo.

Atentamente,

OLGA OJEDA CÁRDENAS
LA TITULAR

c.c.p. Hugo Guzmán Sandoval, Director General de Cooperación Internacional.-Presente
Israel Núñez Birrueta.- Director General Adjunto de Asuntos Regionales y Biodiversidad.- Presente.

HGS/INB/LMO/MJC

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-----Original Message-----
From: Birthe Ivars [mailto:Birthe.Ivars@md.dep.no]
Sent: Monday, May 19, 2003 9:27 AM
To: valerie.normand@biodiv.org
Cc: Guri Tveito
Subject: Access and benefit-sharing - latest developments in Norway

Dear Valerie,

With reference to your request concerning the follow-up of decision VI/24 on access and benefit-sharing as related to genetic resources (and notification no. 2003-40), we have the pleasure to submit the following factual information for the ABS Working Group meeting in December.

The following developments in Norway are relevant with regard to para. 8 c) of the decision. Note that these proposals are subject to acceptance by the Parliament.
The Norwegian government submitted on 9 May this year a legislative proposal to amend the current Patent Law to Parliament. It is expected that the proposal will be dealt with by the Parliament before the summer holidays start on 23 June. The legislative proposal (Ot.prp. nr. 86 (2002-03) reads as follows (free translation from Norwegian, new para. 8b):

"If an invention concerns or uses biological material, the inventor shall disclose in the patent application the country providing such material. If national legislation in the providing country requires prior informed consent before providing such material, the application shall include information on whether such consent has been sought.

In cases where the providing country is different from the country of origin of the biological material, the country of origin shall also be disclosed. Country of origin is defined as the country from where the material is accessed in in situ conditions. In cases where national legislation in the country of origin requires prior informed consent before providing such material, the application shall include information on whether such consent has been sought. If the applicant does not know the country of origin or whether prior informed consent is required, the applicant shall state this fact in the application.

These obligations are applicable even if the inventor has changed the structure of the material. They do not concern human material.

Violations of the requirement to disclose information is punishable under § 166 of the Penal Code. The requirement to disclose information does not affect the handling of a patent application or the validity of a patent."

The information requirements are not applicable to international patent applications submitted through the Patent Cooperation Treaty system, as this would be contrary to the obligations pursuant to the Patent Cooperation Treaty.

Other developments

The Norwegian Government appointed in April 2001 an expert committee assigned to examine Norwegian legislation with the aim to strengthen legal measures for the protection of biodiversity in Norway, included how legislation responds to the issues within the scope of the Convention on Biological Diversity and other relevant international instruments.

Access to genetic resources and benefit-sharing are identified as separate and priority issues in this legislative work as this is an area not yet subject to legislation in Norway. The Committee will naturally use the Bonn Guidelines amongst other instruments and examples as an input to this work. Norway is considered as both a provider and user country of genetic resources, and therefore the mandate of the committee is to propose regulations with regard to both access to genetic resources in Norway and regulations concerning the use of genetic resources originating from other countries when used in Norway (user country obligations).

The committee recently arranged a hearing where relevant stakeholders were invited. The indigenous people (the Sami population) are represented in the reference group of the Committee. The Committee shall present its report to the Government by the 1 June 2004. The report will then have to be followed by a government proposal for new legislation to be adopted by the Parliament.

We hope this information is helpful to you. We will come back to the issue once the Parliament has dealt with the proposals.

Best regards,

Birthe Ivars
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-----Original Message-----
From: Mr.Gamini Gamage [mailto:envgreen@sltnet.lk]
Sent: 17 April, 2003 4:02 AM
To: Mr. Hamdallah Zedan
Subject: sending information on case studies on Access to Genetic Resources

Dear Sir,
I applogize for the delay in reply.
I am sending herewith abstracts of 5 case studies done resently regarding the bio prospecting and economic valuation of Genetic Resources in Sri Lanka. best regards,

Ms. Dakshini Perera,
Research Assistant,
For Director(Biodiversity),
Ministry of Environment and Natural Resources,
Sri Lanka.

Case studies on Access to Genetic Resources and Bio-Prospecting in Sri Lanka

1. Pushpakumara D.K.N.G, Kotagama H.B, Gunaratne L.H.P, Wijesundara S, **An Assessment of Economic Value of Bio (Pharmaceutical Prospecting), Royalty Rate and Appropriation and Their Roles in Bio prospecting.**

   Objective of this study is to economically estimate the pharmaceutical value of the plant genetic resources poo in a natural forest. The Knuckles range which acts as a boundary of the wet and dry zones which, comprises of four major forest formations namely, lowland semi evergreen, mid elevation wet evergreen, mid elevation dry evergreen, montane wet evergreen forests or cloud forests. Data were collected from secondary sources and for further information respective institutions and professional experts were consulted.

   Considering the diversity of the woody plants within the Knuckles range 67 families including 183 genera with 288 species were identified. Among them 85 species were endemic with 3 rare endemic and 12 non endemic rare species. The species richness potential (χ) of Knuckles Range found to be 18. the estimated economic value of pharmaceutical prospecting(Rs. 1768.33/ha/yr) is very law with compared to the foregoing opportunity cost of the land use under tea (Rs. 34 822/ha/yr). The sensitivity analysis on policy variables: rate of royalty, probability of appropriating value and probability of inventing a successful plant based drug show that the foregoing opportunity cost can be compensated if r = o.19, a = 0.5 under 5 in 10000 probability of inventing a successful plant based drug.

2. Pushpakumara D.K.N.G, Kotagama H.B,Marambe B, Gunaratne L.H.P, Wijesundara S, **Evaluate Promote Profitability of Value Added Biodiversity Products Case Studies of *Santalum album* and *Exacum* species.**

   This study basically focused to seen the value adding through it's various usage pathways. Genera *Exacum* represent family Gentianaceae and are about 40 species including 3 endemics. Back ground details are collected form personal communications, indigenous knowledge and from literature available such as newspapers and internet.

   Results show that price of this plants are controlled by salesmen and there is no proper monitoring system for these plants. People mostly buy the plant due to the attractive colour of the flower. Salesmen uprooted these plants directly from the

natural ecosystems and do not tend to reforesting. Therefore proper system should be developed for cropping and selling.

Genera *Santalum* album represent the family Santalaceae. Being an obligate root hemi parasite, throughout its life span, Sandalwood has to be associates with other host species to supplement parts of its C, N and other mineral requirements. These details are planning to collect randomly by observing the external clues of this plant.

The results show that there are no proper monitoring system and standards for the local standards for the local Sandalwood products .therefore only a small quantity of Sandalwood oil is added for products. The extraction procedure is in a preliminary stage and lots of impurities are been added to the oil. There are some evidence of export Sandalwood heartwood and wood carvings illegally.

3. Pushpakumara D.K.N.G, Kotagama H.B,Marambe B, Gunaratne L.H.P, Wijesundara S, **Evaluate Magnitude of Sharing Among Production Participants.**

Three case studies were followed to understand the magnitude of sharing among production participants. Three plants namely Kotalahimbutu *(Salacia reticulata)* Binkohomba *(Munronia pumila)* and Veniwel *(Coscinium fenestatum)* which are used widely in Ayurvedic medicine are selected for this study. According to the Fauna and Flora protection ordinance it is prohibited to export indigenous animals and plants or their parts without permission. But it is enforceable in many cases.

Kotalahimbutu is a popular Ayurvedic medicine for diabetes. Although it is a threaten plant growing in the dry zone of Sri Lanka, it is collected widely from the jungle without any permit. However it is only cultivated in large scall at places like Rjanganaya, Mahiyanganaya and Hambanthota.

Considering the percentage of sharing the collector gets only 11.43% of the profit. The intermediate person who collect the material from the collector and hand it to the whole seller gets 5.71% of the profit. The whole seller gets 17.85% of the profit while 65% of the profit goes to the manufacturer of the final product.

Binkohomba is a small herb. It is considered as a very rare plant which is very difficult to identify. Demand for this plant is so high that the people sell other alike plants as Binkohomba. One Kg of plants will cost about Rs. 2000/= while it costs Rs.7700/= at level of the customer. Considering the magnitude of sharing the collector gets 50.14% of the profit while the intermediate person who collect the material from the collector and transport it to the whole seller gets 12.41% profit.

From the total profit the whole seller gets 14.89% and the manufacturer of the final product gets 22.56%.

Veniwel is a woody climber that commonly found in the rain forests of Sri Lanka. Although it is not a rare plant the wide use for medicine and cosmetically important products has threaten the existence of the plant. Veniwel takes a long time to grow in to the stage of consumption and not cultivated. The plants are collected from the wild. One Kg of plants will cost about Rs. 10/= while it costs Rs.450/= at level of the customer. Considering the magnitude of sharing the collector gets only 6.29% of the profit while the intermediate person who collect the material from the collector and transport it to the whole seller gets 8.17% profit. From the total profit the whole seller gets 21.38% and the manufacturer of the final product gets 64.15%.

4. Pushpakumara D.K.N.G, Kotagama H.B,Marambe B, Gunaratne L.H.P, Wijesundara S, **Potential Profitability of Value Added Products**

The objective of this study is to identify the behaviour of these marketing chains of the two selected bio diversity products namely, Veniwelgata and binkohomba. The information was gathered by interviews.

Venivalgeta is a perennial woody climber with a hard stalk mostly found in the dry zone of Sri Lanka. The collectors sell one kilogram of Venivalgeta to Rs. 30.00 to the intermediate person and he sales it to the whole seller to Rs. 35.00. The wholesaler sales a kilogram of 1foot pieces to Rs. 40.00, 2" pieces to 45.00 and the powder to Rs. 70.00. the manufacturer sales 1Kg of "Dasangalepaya" to 1391.50 and get a profit of Rs. 102.00 per Kg.

Binkohomba is a small perennial flowering plant found in the shrub jungles of the dry zone. The collectors who live in nearby villagers collect the plants from the jungle and sale one kilogram of wet plants to Rs. 2000.00. the intermediate person collect the wet plants dry them and sale them to the wholesaler to Rs. 2500.00 and gets a profit of Rs. 300.00 after reducing transport and labour cost and the weight lost after drying. The wholesaler sales I Kg of the dry plant to Rs. 3000.00 and get a profit of Rs. 100.00 per Kg.

5. Pushpakumara D.K.N.G, Kotagama H.B, Marambe B, Gunaratne L.H.P, Wijesundara S, Gamage G, Silva L. H P , Karaluvinne S.SD.K. **Prospects of Pharmaceutical Prospecting to Finance Biodiversity Conservation in Sri Lanka.**

Identifying mechanisms to finance environmental conservation is crucial to achieve sustainable development. Pharmaceutical prospecting has been touted as a mechanism with prospects to generate revenue to conserve biodiversity. Pharmaceutical prospecting could improve with the use of prior information to guide pharmaceutical prospecting research. Such prior information could be traditional Knoledge on use of biodiversity for medicinal purposes. Sri Lanka is richly bestowed with both biodiversity and traditional knowledge of the use of it for medicinal purposes. This paper through review of the literature and empirical estimation of the willingness to pay the pharmaceutical prospecting, has estimated the complementary value to biodiversity and traditional Knoledge of its use, in Sri Lanka. The Knuckles forest has been used as the demonstrative case for analysis. It is found that pharmaceutical prospecting has reasonable potential to generate revenues to conserve biodiversity in Sri Lanka. Thus it is recommended that legislation, institutions and mechanisms, which are required to establish property rights on biodiversity and traditional knowledge, be expeditiously established to facilitate pharmaceutical prospecting. Given the social and political sensitivity of of pharmaceutical prospecting, broad public consultation should be sought, prior to implementation of pharmaceutical prospecting.

BUWAL Bundesamt für Umwelt, Wald und Landschaft
OFEFP Office fédéral de l'environnement, des forêts et du paysage
UFAFP Ufficio federale dell'ambiente, delle foreste e del paesaggio
SAEFL Swiss Agency for the Environment, Forests and Landscape

Division International Affairs

CH-3003 Berne, January 16, 2003

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Internet: http://www.environment-switzerland.ch

Your reference

Your letter dated

Our reference Py / LAR/C033-0670

Subject **Notification 2002- 096**

Dr
Hamdallah Zedan
Convention on Biological Diversity
World Trade Center
Canada - 393, rue St Jacques Montreal,
Quebec H2

33569

JAN 17 2003

ACTION VN
FILE
INFO GD, CT

Dear Sir, Dear Hamdallah,

In response to the notification addressed by the Secretariat on July 3, 2002 regarding decision VI/20 A paragraph 9 inviting Parties and Governments to submit information on issues referred to in paragraphs 8(a), (b), (c) and (e) of Decision VI/20 A, we would like to inform the Secretariat of the following:

(a) *Use of terms:* On this point we would like to refer to the document **UNEP/CBD/COP/6/INF/40** which represent a valuable background document for the Working Group deliberations on this issue.

(b) and (c) *Other approaches and measures to support compliance with PIC:* Following WSSD decision to negotiate within the framework of the CBD an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilisation of genetic resources, we would like to request the Secretariat to set up a new deadline for comments on those topics by July 1, 2003. This will allow us to take into consideration the outcome of the discussion on WSSD decision that will take place during the MYPOW meeting.

(e) *Capacity building:* The Working Group should consider the Draft Action Plan as well as the possible approach for action and the draft decision developed by the open-ended expert workshop on capacity building for ABS that took place in Montreal in Decembre 2002.

Sincerely yours,

Beat Nobs
Ambassador

Copy: Py, Ka, Ho, LAR

BUWAL Bundesamt für Umwelt, Wald und Landschaft
OFEFP Office fédéral de l'environnement, des forêts et du paysage
UFAFP Ufficio federale dell'ambiente, delle foreste e del paesaggio
SAEFL Swiss Agency for the Environment, Forests and Landscape

International Affairs Division
CH-3003 Berne, September 17, 2003

Telephone: +41313229323
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E-Mail: beat.nobs@buwal.admin.ch
Internet: http://www.environment-switzerland.ch

Your reference

Your letter dated

Our reference NB / C372-0392

Dr Hamdallah Zedan
Executive Secretary
Convention on Biological Diversity
World Trade Center
393 St Jacques Street, Suite 300
Montreal, Quebec
Canada H2Y 1N9

Subject **Notification 2003-040**

Dear Sir,

Please find enclosed the response prepared by Switzerland to the notification addressed by the Secretariat on April 9, 2003 referring to the implementation of decision VI/24 on access and benefit sharing and the follow-up to the Intersessional meeting of the Multi-Year Programme of Work of the Conference of the Parties. This document complements the letter addressed to the Secretariat on January 16, 2003 in response to Notification 2002-096.

Sincerely yours,

Beat Nobs
Ambassador

38372
SEP 18 2003
ACTION GD
FILE
INFO VN, OT

Copy: - OFAG, Monsieur Alvin Kopse
- SECO, Monsieur Andreas Werthmüller
- IGE, Monsieur Martin Girsberger
- intern: Ka, Ho, Py, SAP, LAR

Preparation of the Second Meeting of the Ad'Hoc Open-ended Working Group on Access and Benefit Sharing (1-5 December 2003, Montreal) (see recommendation 5 of MYPOW)

i) Implementation of the Bonn guidelines

Several measures have been undertaken at the Swiss national level in order to support the implementation of the Bonn guidelines.

a) National workshop

In November 2002, the Swiss Agency for Environment, Forest and Landscape (SAEFL) and the Swiss Federal Office for Agriculture (FOA) co-organized a national workshop on ABS for Swiss stakeholders. This workshop had two main objectives. One was to familiarize participants with the International Treaty on Plant Genetic Resources (IT) and the Bonn guidelines and their implications, and the second was to initiate a debate among the stakeholders, on the relevance of these agreements for Switzerland and the consequences of their implementation. The final report of the workshop as well as the documentation is available at: http://www.umwelt-schweiz.ch/buwal/eng/fachgebiete/fg_biotechnologie/information/meeting/ABS/index.html

The main outcome of this workshop can be summarized as follow:

- The IT and the Bonn guidelines are largely supported as useful instruments for the implementation of ABS provisions of the CBD. It is critical to ensure a coordinated follow-up and implementation of these two instruments;
- To achieve the political objectives in terms of environment and multifunctional agriculture, the conservation and the sustainable use of genetic resources should be closely linked
- The government should establish in close collaboration with all stakeholders, national capacity-building programs for managing genetic resources, with the aim of raising users' awareness of the problems and of their obligations.
- The implementation mechanisms should be elaborated in close cooperation with the stakeholders. They should be flexible enough to allow differentiated application that takes into account sectorial particularities and needs. With regard of the implementation of the Bonn Guidelines, a voluntary instrument will need to be developed in the context of a strategy or national framework in order to reinforce the national and international credibility of the stakeholders regarding compliance.
- The development of an international system to protect traditional knowledge should be strongly encouraged. Disclosure of the country of origin of genetic resources and of traditional knowledge was frequently mentioned as a useful measure to guarantee transparency of and respect for the access and benefit sharing provisions in patent applications when the object of the application is or uses genetic resources or traditional knowledge in its development. On the other hand, divergences still exist regarding the form and the status to be given to this measure.

b) Establishment of national working group on ABS

As a first practical outcome of this workshop, a national working group on ABS was set up beginning of 2003 by the Swiss Agency for Environment, Forests and Landscape and the Federal Office for Agriculture. This working group is composed of representatives from governmental and non-governmental stakeholders including academic research, private sector, seed producers and botanical garden. The major tasks of this working group are to:

- identify the specific needs and activities of stakeholder
- Help the stakeholders in the development of sector-based measures
- support co-ordination of information exchange (through the CHM) and promote public and professional awareness on topics related to ABS
- develop a national strategy on ABS with coordinated measures
- Follow international activities within the CBD (especially on the "international regime") and the FAO International Treaty

c) Implementation of sector-based measures

Two projects involving in one case the botanical gardens and in the other case the research community through the Swiss Academy of Sciences have been recently launched. The main goals of

these projects are to promote awareness on ABS issues with emphasis on the Bonn guidelines and to develop concrete voluntary sectorial measures for the implementation of the Bonn guidelines. We will report on the progress at the COP7.

d) Management Tool to support or facilitate the implementation of ABS provisions of the CBD, particularly the Bonn guidelines

At COP6, Switzerland presented the results of a preliminary study commissioned by the State Secretary for Economic Affairs (SECO) which demonstrate the feasibility of establishing certification-like system for bioprospecting activities (see http://www.biodiv.org/doc/meetings/cop/cop-06/other/cop-06-ch-rpt-en.pdf). Based on this outcome and following numerous consultations, SECO has recently launched a new project to develop a Management Tool to support or facilitate the implementation of ABS provisions of the CBD, particularly the Bonn guidelines. This project is organized in 3 steps: 1) Development of the elements of the draft Management Tool, (e.g. a set of substantive requirements to guide ABS practices, a management to guide its application and approaches or options for conformity assessment); 2) Broad international consultation of all governmental and non-governmental stakeholders; 3) Case studies to test the Management tool.

This project will be presented at a side event during the 2nd Meeting of the Ad'Hoc Open-ended Working Group on Access and Benefit Sharing.

ii) Measures to promote the declaration of the source of genetic resources and traditional knowledge

In response to Decision VI/24 C par. 1 and 2, and taking into account other obligations under relevant international agreements, and with the aim to achieve a balanced overall-approach, Switzerland submitted concrete proposals to the Fourth Session of the Working Group on Reform of the Patent Cooperation Treaty (PCT) of WIPO. These proposals were presented as well to the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) and the TRIPS Council.
These proposals would explicitly enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications. More specifically, Switzerland proposed to amend the Regulations under the Patent Cooperation Treaty (PCT) of WIPO to explicitly enable the Contracting Parties of the PCT to require patent applicants, upon or after entry of the international application into the national phase of the PCT procedure, to declare the source of genetic resources and/or traditional knowledge, if an invention is directly based on such resource or knowledge. Furthermore, Switzerland proposed to afford applicants the possibility of satisfying this requirement at the time of filing an international patent application or later during the international phase. In case an international patent application does not contain the required declaration, national law may foresee that in the national phase the application is not processed any further until the patent applicant has furnished the required declaration.
By reference, the proposed amendment to the PCT would also apply to the Patent Law Treaty (PLT) of WIPO. Accordingly, the Contracting Parties of the PLT would be able to require in their national patent laws that patent applicants declare the source of genetic resources and/or traditional knowledge in national patent applications. Based on the PLT, national law may foresee that the validity of granted patents is affected by a lacking or incorrect declaration of the source, if this is due to fraudulent intention.

The proposals submitted by Switzerland were welcomed by many delegations, in particular from developing countries. It is foreseen to further discuss them at the next session of the Working Group on Reform of the PCT of WIPO to be held in November 2003.

Additionally, Switzerland invited WIPO, in close collaboration with the CBD, to consider the establishment of a list of government agencies that would be competent to receive information about patent applications containing declarations of the source. The disclosure and the respective information would allow the Contracting Party providing the genetic resources to verify whether the patent applicant has fulfilled the requirements and procedures of its national system of PIC and whether provision has been made for fair and equitable benefit sharing.

The full Swiss proposal is available at :
http://www.wipo.int/pct/en/meetings/reform_wg/pdf/pct_r_wg_4_13.pdf

In the context of the revision of the Federal Law on Patents, an administrative working group has been established by the Federal Council under the responsibility of the Swiss Federal Institute of Intellectual Property to clarify a certain number of issues linked with the declaration of the source of genetic resources and traditional knowledge and its integration in the Federal Patent Law.

iii) Considerations on the process, nature, scope, elements and modalities of an international regime on ABS

With regard of implementation of the ABS obligations of the Convention on Biological Diversity, the position of Switzerland can be summarized in the following 3 points:

1. Priority should be given to national implementation of the Bonn guidelines.

   Switzerland supports a voluntary ABS approach based on the rapid implementation of the Bonn guidelines (see i). Indeed in our view such an approach presents the following advantages:
   - Quick and easy participation of all the stakeholders involved in the use of genetic resources;
   - Fast implementation, allowing considerable pertinent experience to be gained over a relatively short period of time;
   - Flexibility which allows specific measures adapted to the needs of each group of users

2. National and international measures should be established to promote the declaration of the source of genetic resources and traditional knowledge (see ii)

3. If relevant gaps are identified by providing Countries, Switzerland is ready to actively discuss any proposal to improve the implementation of the CBD within the negotiation of an International Regime on ABS.

Based on this and in the absence of any substantive proposal, Switzerland does not have at this stage any particular view regarding the scope, elements and modalities of an International regime except that it should addressed both access to genetic resources and benefit and should focus only on issues which are not properly covered by the Bonn guidelines. It is also premature to define the nature of the International Regime since this will depend on its scope and modalities. Regarding the process, the first step should be to identify the gaps that would require additional action at the international level. This should be made in close coordination with relevant ongoing activities under the IT and WIPO. On the basis of the outcome of this analysis, the COP should decide on the appropriate measures to address these gaps.

Convention on Biological Diversity

Secretariat

ANNEX I

Database on Access and Benefit-sharing Measures

DATA ENTRY FORM

General guidelines for completing the form

Parties and relevant organisations are invited to fill out this form in order to identify the main characteristics of the measures undertaken to address access to genetic resources and the fair and equitable sharing of benefits, in accordance with Article 15 of the Convention. Parties and relevant organisations are also encouraged to forward to the Secretariat **a copy of the measure, preferably in electronic form** (Word format would be appreciated), which will be accessible through the Clearing House Mechanism, for information purposes.

In the event that more than one measure has been adopted at the national or regional level, Parties and relevant organizations are requested to fill in a separate form for each different type of measure.

Identification of level and name

1) In the second column, please indicate whether the measure has been undertaken at the regional, national, sub-national, community or local level.

	Level
Regional	
National	X
Sub-national	
Community	
Local	
Other	

2) Please provide the name of the region or of the country and, if applicable, of the sub-national level (e.g. State, Province, etc) or community or locality within that country to which the measure applies:

Switzerland

Area of activity

Please indicate whether the measure is general or whether it has been undertaken to apply to specific sectors (e.g. agriculture, forestry) and/or whether it is meant to apply to specific categories of users (e.g. industry, botanical gardens, research institutes, *ex situ* collection holders).

To: All CBD National Focal Points /...

UNEP United Nations Environment Programme
Tel: (+514) 288-2220
Fax: (+514) 288-6588
website: www.biodiv.org
e-mail: secretariat@biodiv.org
World Trade Centre
393 Saint-Jacques Street, Suite 300
Montréal, Québec, Canada H2Y 1N9

General	
Sectoral	X
Specific to a category of users	

If sectoral and/or specific to a category of users, please specify the sector and/or category of user: **Agriculture**

Type of measure in place and official title

Please indicate whether the measure undertaken has taken the form of a national or regional strategy, policy, legislation, regulation, community management plan, guidelines or a code of conduct on access and benefit-sharing.

Strategy	X
Policy	X
Legislation	
Regulation	X
Community management plan	
Guidelines/Code of conduct	
Other	

If other, please specify:

Please provide the official title of the measure:
National Plan of action for the protection and sustainable use of plant genetic resources for food and agriculture

---

Scope

Please indicate whether the policy, strategy, legislation, regulation, community management plan, guidelines or code of conduct related to access and benefit-sharing is within the framework of a broader measure dealing with sustainable development, environment or biodiversity or whether it is a distinct measure focussing only on access and benefit-sharing:

Sustainable development	X
Environment	
Biodiversity	
Access and Benefit-sharing	

Coverage

Please indicate which of the following specific issues related to access and benefit-sharing are covered by the measure:

Access to Genetic Resources	X
Equitable Sharing of benefits arising out of the utilization of genetic resources	X
Equitable sharing of benefits from the utilization of traditional knowledge, innovations and practices	X
Intellectual property rights related to genetic resources	
Intellectual property rights concerning the protection of traditional knowledge, innovations and practices related	

to genetic resources	
Customary or traditional use of genetic resources	**X**
Other	

If other, please specify:

Current status of the measure

Where applicable, please indicate whether the measure is still in draft form, or whether it has been adopted and has entered into force and if so, at which date it has been adopted and/or has entered into force.

Status	Date (Day/Month/Year)
Draft	
Adopted	X
Entered into force	01.01.1999

38391

defra
Department for Environment Food and Rural Affairs

SEP 19 2003

ACTION ED
FILE
INFO VN, OT

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Mr Hamdallah Zedan
Executive Secretary
Secretariat of the CBD
Montreal
By fax: +001 514 288 6588

19th **September 2003**

Dear Mr Zedan

CONVENTION ON BIOLOGICAL DIVERSITY: PROVISIONS ON ACCESS AND BENEFIT SHARING/USE OF BONN GUIDELINES

At the Inter-sessional meeting on the Multi-Year Programme of Work of the Conference of the Parties in March 2003, countries were invited to provide information to the Executive Secretary on experience gained in the use of the Bonn Guidelines on access and benefit sharing, taking into consideration information to be provided by Parties pursuant to COP decision VI/24 A.

This response sets out relevant experience in the United Kingdom.

First, by way of background, recent years have seen increased interest in the conservation and sustainable use of genetic resources and growing acknowledgement of their importance for sustainable development at international, regional and individual country level.

In the international field, besides the ongoing discussion in the CBD, the work in other fora, including WIPO and the OECD, is highly relevant. In the FAO, agreement on the International Treaty on Plant Genetic Resources for Food and Agriculture and the work on farm animal genetic resources have been major features. In the view of the UK the International Treaty is a significant achievement: its Multilateral System will make an important contribution to the conservation and sustainable use of PGRFA as well as providing facilitated access to the material it covers.

The UK has been active in these international negotiations with the aim of achieving instruments that are both helpful for policy objectives and which are also pragmatic and workable in a variety of situations. In parallel the UK has been developing policies nationally in the light of international developments in these various fora and in consultation with a cross section of stakeholders.

More specifically in 2002 the UK carried out the first part of a two stage review of policy on the conservation and sustainable use of genetic resources. A wide range of stakeholders was consulted in a review of practice in the UK which also took account of arrangements in other European countries. A conference brought together users and suppliers of genetic resources across the UK from the plant, animal and microbial world - the first time that the three domains had been drawn together in this way. (I enclose the executive summary from this review. The full report is available on the Defra Genetic Resources webpage at http://www.defra.gov.uk/farm/geneticresources/)

Taking forward the recommendations of the review in close collaboration with stakeholders, the UK has produced a policy statement establishing for the first time a strategic approach to the conservation and sustainable use of genetic resources for food and agriculture in the UK (I enclose a copy of the final draft of this strategy which will be published shortly on the Defra Genetic Resources web page). The first step in a rolling programme of actions - a project to establish an inventory of genetic resources relevant to food and agriculture in the UK - is underway and the results will be published next year.

In 2001 the UK established and financed an independent Commission on Intellectual Property Rights, which was asked to consider, amongst other things, how the international framework of rules and agreements might be improved and developed, for instance examining the relationship between IPR rules and regimes covering access to genetic resources (details of the Commission's work and final report are on the website: http://www.iprcommission.org/). In its final report, amongst other things the Commission recommended amendments to patent rules to allow the country of origin of any genetic resources used in inventions to be declared as well as establishment of a clearing house for this information; similar ideas are now actively under consideration at UK and EU level and in the TRIPS Council.

In 2002 the UK established a web-based National Focal Point for ABS providing information to assist any individuals or organisations that may wish to access genetic resources in the UK held both *in situ* and *ex situ*. The Bonn Guidelines on ABS have been published on the Defra website.

The Bonn Guidelines themselves build on work coordinated by the Royal Botanic Gardens, Kew and funded by the UK Department for International Development. The '*Pilot Project for Botanic Gardens*' involved 28 botanical institutions from 21 countries sharing ideas on best practice, and developed a set of voluntary '*Principles on Access to Genetic Resources and Benefit-Sharing*' to harmonise institutional policies, as well as a set of more detailed Common Policy Guidelines. Kew has continued its work in practical ABS implementation and recently produced '*The CBD for Botanists*', a simple user-

friendly guide to the CBD and its provisions on ABS for botanical collection managers.

This year will see work begin on the second part of the two stage review of genetic resources policy in the UK. A consultant has been appointed who will consult stakeholders on the operation of CBD ABS provisions in the UK including an examination of the influence of the Bonn Guidelines on the practice of UK users and suppliers of genetic resources (a copy of the terms of reference of this review are enclosed). Both users and providers of genetic resources in the UK will be involved and the review will provide valuable information on their experiences in operating ABS. It will be published.

I hope that you find this letter and attachments of use. If you need any additional information or explanation please do be in touch.

Best wishes

Yours sincerely, Martyn J Ibbotson.

Martyn J Ibbotson
Head of Genetic Resources and Sponsorship Unit
Research Policy International Division

UK DEFRA REVIEW OF POLICY ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Project Manager: Claire Wilding

1. EXECUTIVE SUMMARY

1.1. The need for a comprehensive policy

Genetic resources are genetic material of current or potential use. The need for a new, comprehensive policy on conservation and sustainable use of genetic resources for food and agriculture (GRFA) is driven by the current lack of a strategic policy; the need to implement new and existing international obligations and commitments; and the creation of Defra, linking biodiversity and agriculture concerns with an emphasis upon sustainable development.

A policy is needed to:

- co-ordinate existing activities
- meet international obligations and commitments
- conserve agricultural biodiversity and support wider biodiversity
- support breeding programmes for sustainable agriculture
- support scientific research
- provide an insurance policy for the future
- conserve our heritage
- provide a resource for other countries

1.2. The policy review

This report is the result of a policy review that extended to all genetic resources relevant to food and agriculture, including plants, animals and microbes. Defra is responsible for policy in this area for England and Wales. The review process involved interviews with stakeholders; a conference bringing together stakeholders to determine priorities for a GRFA policy; a review of international commitments; and a review of GRFA policy in three other European countries.

1.3. Current situation

A number of organisations are involved in activities for the conservation and sustainable use of GRFA, including Defra, government agencies, research institutes, NGOs and industry. Defra currently has no strategic policy on GRFA. Responsibility is split between Research Policy and International Division, for plants and microbes, and a specialist post in Sustainable Agriculture and Livestock Products Directorate, dealing with farm animals. A number of other divisions are involved in activities and policies relevant to GRFA. Defra spends 545 K on supporting ex situ plant collections, and a

negligible amount on animal collections. A number of Defra funded research projects are directly or indirectly related to GRFA.

1.4. Recommendations for a framework for GRFA

This report recommends development of a framework for future policy initiatives, consisting of eight key objectives. These would be achieved through a detailed programme covering plant, animal and microbial genetic resources, not yet costed, to be developed with stakeholders. Full recommendations and analysis are given in section 7.

1.4.1. A new framework for conservation and sustainable use of GRFA

Recommendation 1: A framework for conservation and sustainable use of GRFA should be developed as a reference point for further work by Defra and other organisations. Its aim should be the conservation and sustainable use of plant, animal and microbial genetic resources to support sustainable agriculture and horticulture, environmental improvements, rural development, scientific research and conservation of heritage and biodiversity, now and in the future.

Recommendation 2: The framework should be implemented through a detailed policy consisting of rolling programmes for plants, animals and microbes, developed in consultation with stakeholders and subject to available resources.

1.4.2. Scope of policy

Recommendation 3: GRFA policy should focus upon species, varieties and breeds that are not adequately covered by policies on biodiversity, fisheries and forestry.

Recommendation 4: Defra should work with DTI, DoH and other relevant departments to determine who should be responsible for microbial and genetic stock genetic resources, and to develop a suitable policy for their conservation and sustainable use.

Recommendation 5: Defra should work with the Forestry Commission where forest genetic resources and agricultural genetic resources overlap.

1.4.3. Main objectives of the framework

Recommendation 6: The main objectives of a framework for GRFA should be to:

- Co-ordinate activities and improve co-operation
- Facilitate sharing of information on GRFA
- Compile a National Inventory of GRFA
- Support conservation of ex situ GRFA
- Support conservation of in situ GRFA
- Support characterisation and evaluation of GRFA, with particular focus upon plant and animal health, environmental improvements, animal welfare and sustainable agriculture
- Raise awareness of the importance of GRFA with the public, scientific community, breeders, consumers and food industry
- Support GRFA through other Defra policies and programmes

These objectives are expanded in 1.5 below. Responsibility for achieving these objectives would be shared between Defra and stakeholders. The objectives take account of stakeholder priorities and the commitments and priorities of international obligations relevant to GRFA.

1.5. Recommendations for implementation of the framework

The following recommendations highlight key areas for action identified by the policy review. These need to be developed further in the context of the programmes on plants, animals and microbes, subject to available resources and in consultation with stakeholders.

1.5.1. Co-ordinate activities and improve co-operation

7. Defra should work through existing stakeholder groups. Any initiative to appoint a national facilitator should come from stakeholders.
8. Defra should encourage regular meetings of representatives of the three communities to discuss issues of common interest and give feedback on GRFA policy.
9. UKPGR (UK Plant Genetic Resources Group) should continue to be the main interface between Defra and plant genetic resource stakeholders. Where relevant, Defra should consult other plant genetic resource interest groups not covered by UKPGR, e.g. nature conservation organisations.
10. A permanent National Steering Committee for Farm Animal Genetic Resources should be established.
11. Representatives of both mainstream and at risk farm animal breeds should be consulted.
12. The UK National Culture Collection and the UK Federation of Culture Collections should both be used to communicate with stakeholders in the microbial sector.

1.5.2. Facilitate sharing of information on GRFA

13. Defra should develop a national information system for GRFA, in order to provide information on activities by Defra and other organisations and links to resources including collection databases. The site should link up existing information resources.
14. A review of database projects both within and outside Defra should be carried out, drawing together information on all the current initiatives, with the aim of developing links and synergies.
15. Consideration should be given to developing the CBD National Focal Point as the portal for such an information system.

1.5.3. Develop a National Inventory of GRFA

16. Compilation of a national inventory of GRFA collections and sites should be a key priority. This should be done in collaboration with the devolved administrations and stakeholders, and should be made publicly available where appropriate.

1.5.4. Support conservation of ex situ GRFA

17. Key ex situ collections should be identified.

18. Defra should only commit to long term funding of collections where stringent conditions are met. In general, Defra should support key ex situ collections through other means, e.g. supporting research and co-ordinating activities of other organisations.

1.5.5. Support conservation of in situ GRFA

19. The policy should cover in situ plant GRFA, including wild growing plants, landraces and conservation varieties. In situ plant genetic resources should be included in a national inventory, as a basis for determining what further work is necessary.

20. Defra should work with nature conservation organisations on in situ plant GRFA.

21. Defra should consider the desirability of supporting indigenous breeds at risk where they have a positive contribution to make to the environment and heritage value of the countryside, for example, through the England Rural Development Programme. The planned consultation on the future of rural development programmes could provide an opportunity for seeking stakeholder views on the relative merits of this as against other objectives.

1.5.6. Support characterisation and evaluation of GRFA, with particular focus upon plant and animal health, environmental improvements, animal welfare and sustainable agriculture

22. Defra should co-ordinate stakeholders to develop a programmed approach to characterisation and evaluation of GRFA.

23. For plants, public funded development of GRFA is required to develop new genetic material for use in crop plants. Defra should learn from the German National Evaluation Programme, as a model for industry and government working together.

24. Defra should support development of GRFA, including for mainstream farm animal breeds, in order to meet objectives other than direct performance, such as animal health and welfare, biodiversity, reduced environmental emissions and development of industrial crops to support environmental objectives.

1.5.7. Raise awareness of the importance of GRFA with the public, scientific community, breeders, consumers and food industry

25. Defra should work with stakeholders to raise awareness of the importance of GRFA. Awareness raising should be linked to creation of markets to support GRFA.

26. This report should be published in order to communicate the importance of GRFA and the activities undertaken by government and others to conserve and sustainably use GRFA.

1.5.8. Support GRFA through other Defra policy and programmes

27. GRFA policy and biodiversity policy should be closely linked in order to identify possible synergies.

28. A key priority for future work should be a review of Defra policies impacting on GRFA, with the aim of building upon synergies and reducing or removing conflicts.

29. The review of policies should focus in particular upon the negative impacts identified by stakeholders of Defra policies upon breeds at risk.

1.5.9. Organisation of policy within Defra

30. The framework for GRFA should be dealt with by the Sponsorship and Genetic Resources Unit of Research Policy and International Division (RPID), working in close collaboration with Sustainable Agriculture and Livestock Products Directorate (SALPD). Consideration should be given to the best location of the Genetic Resources Unit within Defra, given the possible synergies with biodiversity and other policies. The Unit should be consulted by other divisions where policy decisions may impact upon GRFA policy.

31. Development and implementation of detailed policy on farm animal genetic resources should be the responsibility of the UK National Co-ordinator for farm animal genetic resources in SALPD.

32. Development and implementation of detailed policy on plant genetic resources should be the responsibility of the Sponsorship and Genetic Resources Unit in RPID.

33. Work on microbial GRFA should be the responsibility of the Sponsorship and Genetic Resources Unit of RPID. The Unit should work with DTI, in particular on the issue of long term support for microbe collections. More detailed policy for microbial GRFA should not be developed prior to the completion of the Office of Science and Technology's current review of policy for support of collections.

Review of the implementation of the Access and Benefit Sharing arrangements of the Convention on Biological Diversity

Terms of Reference

Project Manager: Fernando Latorre

The project

Rationale

1. To assist in meeting the UK's international obligations coherently and efficiently, and prior to consideration of any further policy measures, Defra is carrying out a review of the current situation in the UK on access to genetic resources and the equitable sharing of benefits arising from their use (ABS) pursuant to the Convention on Biological Diversity (CBD). This review represents the second part of a two-stage process. The first stage, a UK Policy Review on Genetic Resources for Food and Agriculture was carried out by Claire Wilding for Defra in 2002. This review will focus on the current state of implementation regarding ABS arrangements in the UK. Both reviews will enable Defra to get a better understanding of the present situation in the UK regarding genetic resources.

Objective and Scope

2. The aim of this review is to report on the efforts of different stakeholders, both providers and users, of genetic resources of all types (plants, animal and microbial but not human) in the most relevant sectors to comply with the ABS requirements of the CBD.

Background

3. The UK is involved in several international negotiations with relevance to the issue of biological diversity and genetic resources and is Party to a number of international instruments relevant to the subject. The UK participates actively in meetings of the Convention on Biological Diversity, the International Treaty on Plant Genetic Resources for Food and Agriculture, the World Intellectual Property Organization's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore and the World Trade Organization's Committee for Trade and Environment and Council for Trade Related Aspects of Intellectual Property Rights.

CBD: Access and Benefit Sharing

4. The UK, in addition to the general obligation to report on the implementation of the 1992 Convention on Biological Diversity (CBD) pursuant to its Article 26, has a number of international commitments related to access to genetic resources and benefit sharing in the context of the CBD laid out in Articles 8(j), 15, 16.3, 19.1 and 19.2. Moreover, the CBD Conference of the Parties (COP) has encouraged Governments to explore, develop and implement guidelines and practices, in

collaboration with relevant stakeholders, to ensure benefit-sharing (Decision III/15, paragraph 5), and to include in their national plans or strategies and legislation measures for the equitable sharing of benefits arising out of the use of genetic resources (Decision III/9, paragraph 2 (c)). The COP has also urged recipient countries to adopt measures to support efforts made by providers of resources to ensure that access to genetic resources is subject to Articles 15, 16 and 19 of the Convention (Decision V/26 A, paragraph 4 (c)). COP 6 invited Parties and Governments to use the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization when developing and drafting legislative, administrative or policy measures on ABS, and contracts and other arrangements under mutually agreed terms for ABS and invited Parties to provide financial and technical assistance to support developing countries in implementing the Bonn Guidelines (Decision VI/24A, paragraphs 4 and 5).

5. Finally, and perhaps more importantly, COP 6 also called Parties to make available to the Executive Secretary, detailed information on the measures adopted to implement access and benefit-sharing as well as other information such as that listed in Decision V/26, paragraph 12 (which notes that there is a particular need for more information regarding, among others, user institutions, the market for genetic resources, non-monetary benefits, new and emerging mechanisms for benefit sharing, incentive measures and 'intermediaries') (Decision VI/24 D, paragraph 6).

6. Furthermore, paragraphs 44(n) and (o) of the Plan of Implementation agreed at the World Summit on Sustainable Development in Johannesburg in August 2002, have respectively, reinforced those commitments and set an additional mandate, by calling signatory countries to:

> "(n) Promote the wide implementation of and continued work on the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of their Utilization, as an input to assist the Parties when developing and drafting legislative, administrative or policy measures on access and benefit-sharing as well as contract and other arrangements under mutually agreed terms for access and benefit-sharing".
>
> "(o) Negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources".

7. Developed countries have taken a variety of means to implement the CBD provisions on ABS. The UK gives effect to its obligations under the CBD by administrative measures and has not enacted specific legislation with respect to ABS arrangements. Defra is anxious to ensure that there are no deficiencies in implementing these provisions for both providers and users of genetic resources and so is reviewing current practice. In addition, there have been significant initiatives in this field, (e.g. the Principles and Common Policy Guidelines on ABS for Botanical Institutions <http://www.kew.org/conservation/agrbs-policy.html>) which should be taken account of during the current review.

8. Whilst the Bonn Guidelines are a relatively recent innovation (April 2002), the UK believes that they are a most useful basis for giving practical effect to access and benefit sharing. It would therefore be helpful to identify current experience on anticipated use of the Guidelines or similar mechanisms in the context of the Review.

Methodology

9. The present review will entail carrying out a survey of the state of affairs in the UK regarding the implementation of the ABS provisions of the CBD paying particular attention to the use of the voluntary "Bonn Guidelines".

10. In order to carry out that survey, first, the main stakeholders based in the UK will need to be identified and a detailed programme of consultations will have to be prepared. Secondly, a wide consultation with those stakeholders will be undertaken, chiefly through questionnaires and interviews - we are aiming for as comprehensive a consultation as possible. Among the stakeholders to be consulted there should be representatives from the public sector at national and regional level, universities and research institutions, botanical gardens, museums, NGOs and the private sector (including the pharmaceutical industry, the cosmetics industry, the natural medicines industry, the horticultural industry and the agrifood industry).

Outputs

11. In essence, the review will try to ascertain to what extent the ABS provisions of the CBD are known, to what degree, if at all, the Bonn Guidelines are influential, and what experiences of ABS the stakeholders have had. It will also provide an opportunity to the relevant stakeholders to identify best practices and offer their opinion on the subject, which will inform policy development in Defra.

12. The review will provide:

- a description of the current situation in the UK regarding the implementation of arrangements on access to genetic resources and benefit-sharing under the Convention on Biological Diversity;
- an analysis of such information gathered in the survey identifying what the problems and needs are, if any;
- conclusions and recommendations to government and the rest of stakeholders on how key concerns could be better addressed.

13. The aim is to complete the review by the spring of 2004.

DRAFT

FRAMEWORK FOR THE CONSERVATION AND SUSTAINABLE USE OF GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Background

What are genetic resources?

Genetic resources are genetic material of current or potential use. This framework is concerned with genetic resources for food and agriculture (GRFA), which includes mainstream farm animal breeds; breeds at risk; cultivated plants; landraces; wild relatives of cultivated plants; plants of potential use for food and industrial purposes; and micro-organisms relevant to food and agriculture. Genetic resources exist both *in situ* (living animals, plant and micro-organisms in their natural environment, including on farm); and *ex situ* (outside their natural environment, e.g. in a genebank). Genetic resources can be conserved in a variety of forms, including as whole plants, animals and micro-organisms, seed, embryos, semen, and replicable parts such as genomes and DNA.

Why conserve genetic resources?

Genetic resources are an important component of biodiversity, an important resource for both the UK and other countries, and hold potential benefits for farmers, industry and the public at large. Plants, farm animals and micro-organisms may contain useful genetic traits that can be identified and used in breeding programmes aimed at meeting the challenges of new diseases, environmental pressures or changing consumer demands. They also support scientific research. Some genetic resources should be conserved for cultural reasons, as part of our heritage.

Why is this framework needed?

GRFA are not adequately covered by the UK Biodiversity Action Plan. A framework is needed to support the implementation of international agreements concerning genetic resources to which the UK is a party, including the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture. More importantly it is in the national interest to develop a strategic approach to the conservation and sustainable use of GRFA. GRFA are central to the achievement of Defra's aim of sustainable development and for our policy on sustainable agriculture. They are an important tool for meeting a wide range of other Defra objectives, including protecting the rural environment, promoting sustainable rural economies, promoting sustainable and adaptable farming, promoting sustainable management of natural resources and ensuring high standards of farm animal health and welfare. A framework is also needed in order to better

co-ordinate the many activities already carried out by government, researchers, NGOs and others.

The framework does not cover fish or forest genetic resources. Fish genetic resources are managed by the Environment Agency and through the Common Fisheries Policy. Forest genetic resources are the responsibility of the Forestry Commission.

The process for developing the framework

This framework is the result of a policy review on conservation and sustainable use of GRFA. The full report of the policy review is available at:

http://www.defra.gov.uk/farm/geneticresources/grfareport.pdf

The report's annexes can be found at:

http://www.defra.gov.uk/farm/geneticresources/annexes.pdf

Framework for Conservation and Sustainable Use of Genetic Resources for Food and Agriculture (GRFA)

This Framework has been developed in full consultation with a representative group of stakeholders (see Annex I) and represents an agreed statement of common intent. It applies to England and Wales. **Defra** will work alongside officials of the **Scottish Executive** and **Northern Ireland and Welsh Assemblies** to facilitate a co-ordinated approach across the UK.

Aim: The conservation and sustainable use of, and facilitated access to, plant, farm animal and microbial genetic resources, to support sustainable agriculture and horticulture, and to support related environmental improvements, rural development, scientific research and conservation of heritage and biodiversity, now and in the future.

The objectives of the framework are long term, to be achieved over 10 years or more. All stakeholders have a role to play in the achievement of those objectives. The objectives are to:

1. Co-ordinate activities and improved co-operation

Bodies already exist through which co-operation between stakeholders and co-ordination of activities takes place. At the national level, they include the **UK National Culture Collection**, the **UK Plant Genetic Resources Group** and the proposed **National Steering Committee for Farm Animal Genetic Resources**. At the international level, the **European Culture Collections Organisation**, the **European Co-operative Program for Crop Genetic Resources Networks** and the **European Regional Focal Point on Farm**

Animal Genetic Resources are important. A list of other important national and international organisations with a direct interest in the conservation and sustainable use of GRFA is at Annex II. **Defra** will work with these bodies to help improve co-operation between stakeholders within and between the plant, farm animal and microbial sectors.

2. Facilitate sharing of information on GRFA

A wide range of stakeholders, including **collection holders, researchers, nature conservation organisations, breed societies** and **NGOs**, hold information on GRFA and make it available to others through a range of databases. It is their responsibility to maintain and up-date such databases. **Defra** will seek to add value to this, including through the development of a single portal through which all such information on GRFA can be accessed by stakeholders in the UK and overseas.

3. Compile and maintain a National Inventory of GRFA

No inventory of GRFA available in the UK currently exists. **Defra** will develop such an inventory, which will be as complete as possible, covering both *in situ* and *ex situ* GRFA, and publish it on the web. The inventory should be dynamic and will be up-dated through appropriate monitoring procedures. Input will be required from a wide range of stakeholders, including **other government agencies, researchers, collection holders** and **NGOs.**

4. Support conservation of *ex situ* GRFA

Conservation of *ex situ* GRFA is the responsibility of **research councils, collection holders** and **researchers**. **Defra** will seek to assist these actors through co-ordination. In addition, and in consultation with stakeholders, **Defra will** identify key collections whose development may benefit from Defra support. *Ex situ* conservation of GRFA should be a complimentary activity to *in situ* conservation.

5. Support conservation of *in situ* GRFA

In situ conservation of GRFA is largely the responsibility of **farmers, breed societies, nature conservation bodies** and **NGOs. Defra** will, in consultation with stakeholders, consider the extent to which it could add value to this activity. **Defra** will also develop a policy on *in situ* conservation of plant and microbial genetic resources, working with stakeholders and, in particular, relevant nature conservation bodies such as **English Nature**, the **National Trust, national park authorities, wildlife trusts** etc. Policies on *in situ* conservation of GRFA should have regard for ecosystems. Complimentary *ex situ* measures should be taken where appropriate.

6. Support characterisation and evaluation of GRFA

Characterisation and evaluation of GRFA is a responsibility for **levy bodies, research organisations, collection holders, farm animal and plant**

breeders, breed societies and **Defra**. It should have particular focus on plant and farm animal health, environmental improvements, farm animal welfare and sustainable agriculture. **Defra** will seek to co-ordinate these efforts into a programmed approach. Within such an approach, the **private sector** and **levy bodies** should focus on commercial benefits, such as performance traits, while **Defra** should focus on public goods benefits.

7. Raise awareness of the importance of GRFA

All stakeholders should contribute to raising awareness of the importance of conservation and sustainable use of GRFA with the public, scientific community, breeders, consumers, food industry, trainers within agriculture and within government. **Defra** will seek to co-ordinate and support activity, working closely with, in particular, **NGOs, farm parks, horticultural and botanical gardens**, relevant **museums**, the **retail sector** and **consumer groups**.

8. Support GRFA through other Defra policies and programmes

With input from stakeholders the **Genetic Resources and Sponsorship Unit** of Defra should seek to influence, as far as possible, other **Defra** policies and programmes and the policies and programmes of other government departments to be supportive of the conservation and sustainable use of GRFA.

Implementing the framework

All stakeholders are encouraged to use this framework in the development of their own plans and priorities for the conservation and sustainable use of GRFA. For its part, Defra, in consultation with stakeholders and the devolved administrations, will develop detailed policies separately for the plant, farm animal and microbial GRFA, seeking integration between the sectors where possible. Defra will also develop a rolling programme of actions, which will be prioritised and implemented in the light of available resources.

Work on microbes will not be carried out before the conclusion of the Office of Science and Technology's review of collections, and will take into account the findings of that review.

This Framework and its associated policies should be evolutionary and dynamic. Progress against the objectives outlined above will be reviewed regularly with stakeholders. Together with stakeholders, Defra will aim to carry out a detailed review of its policies on the conservation and sustainable use of GRFA every 5 years.

UK Department for Environment Food and Rural Affairs
Genetic Resources and Sponsorship Unit
September 2003

II. SUBMISSIONS FROM NON PARTIES

United States Department of State

Bureau of Oceans and International Environmental and Scientific Affairs

Washington, D.C. 20520

January 30, 2003

Mr. Hamdallah Zedan
Executive Secretary
Convention on Biological Diversity
World Trade Center
393 Saint-Jacques Street, Suite 300
Montreal, Quebec, Canada H2Y 1N9

Re: Information for the Second Meeting of the Ad Hoc Open-Ending Working Group on Access and Benefit-sharing, December 1-5, 2003

Dear Mr. Zedan:

In Notification 2002-057, dated June 27, 2002, the Secretariat of the Convention on Biological Diversity (CBD) invited, *inter alia*, governments to submit information on the issues referred to in Paragraph 8(a), (b), (c) and (e) of decision VI/24A of the Conference of the Parties. I am pleased to send you herewith the submission of the Government of the United States of America, which is intended to be made available to the Ad Hoc Open-Ending Working Group on Access and Benefit-sharing for its second meeting in December 1-5, 2003.

Sincerely yours,

Christine Dawson
Senior Conservation Officer for Biodiversity
U.S. Focal Point for the Convention on Biological Diversity
Office of Ecology and Terrestrial Conservation

Enclosures: Submission of the Government of the United States with attachments

Information for the Second Meeting of the Ad Hoc Open-Ending Working Group on Access and Benefit-sharing, December 1-5, 2003

Submitted by the Government of the United States of America

In Notification 2002-057, dated June 27, 2002, the Secretariat of the Convention on Biological Diversity (CBD) invited, *inter alia*, governments to submit information on the issues referred to in paragraph 8(a), (b), (c) and (e) of decision VI/24A of the Conference of the Parties. These provisions under paragraph 8 read as follows:-

a. Use of terms, definitions and/or glossary, as appropriate;

b. Other approaches as set out in decision VI/24 B;

c. Measures, including consideration of their feasibility, practicality and costs, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted in Contracting Parties with users of genetic resources under their jurisdiction; and

e. Needs for capacity-building identified by countries to implement the Guidelines.

The Government of the United States of America appreciates the opportunity to submit the information set forth below and in the attachments on these points.

I. Use of terms, definitions and/or glossary, as appropriate

In March 2002, the CBD Secretariat prepared a draft on possible definitions for terms used in the Bonn Guideline on Access to Genetic Resources and Fair and Equitable Sharing of the Benefit Arising out of their Utilization (the "Bonn Guidelines). The general and specific comments provided below relate to those proposed draft definitions. Overall, we believe that a glossary of terms would be of more value than adding definitions to the Bonn Guidelines. A glossary would give governments and stakeholders the flexibility that they will need to use effectively the Bonn Guidelines.

The United States Government has the following suggestions, regardless of whether a glossary or definitions within the Bonn Guidelines are agreed upon.

General Comments

1. Several of the terms are sufficiently clear in the context of the provisions in which they are found to not require any further elaboration. We believe that the terms below are not meant to be technical nor are they intended to take on any meanings other than their common, ordinary meanings. Therefore, the following terms do not to be further defined or included in a glossary.

- "Entity" is only used in Paragraph 36(a) and is part of an indicative list of possible information that might be requested in a prior informed consent process.

- "Voluntary nature" is used only in Paragraph 7(a) and already provides its own definition, i.e., to be used to "guide both users and providers of genetic resources on a voluntary basis". If this term is retained, we believe the second sentence should be deleted because otherwise it could suggest an obligation for Parties to give reasons for deviating from these voluntary guidelines.

- "*Ex situ* collection" is found only in Paragraph 32 and there it clearly implies a collection of materials that is not *in situ*. Furthermore, CBD Article 2 defines "*ex situ* conservation" to mean "the conservation of components of biological diversity outside their natural habitats."

2. The term "derivatives" is found in Paragraph 36(l), Paragraph 44(i) and Appendix I (B), Paragraph 2. We believe the term has no commonly accepted definition. The CBD Secretariat has not proposed a definition for this term. In each case, the term is included as part of an indicative list. Its meaning will be determined on a case-by-case basis by the provider and the user as part of their mutually agreed terms. Thus, we do not think a definition is needed or would be helpful.

3. The terms "stakeholders" and relevant "stakeholders" appear in a variety of provisions throughout the Bonn Guidelines, especially in Part III (Paragraphs 17-21). We believe that the guidelines should not provide a technical meaning to that term, but rather leave it to each country to determine the appropriate stakeholders on a case-by-case basis in accordance with existing national laws, regulations and policies.

Specific Comments

Our comments about the specific language proposed by the CBD Executive Secretariat are set forth below. Our recommended **additions are indicated by underlined bold text** and [deletions by brackets].

Access to genetic resources

"Access to genetic resources" means**, in accordance with terms mutually agreed by the provider and the user, the granting of permission by a provider to the user** [the admission] for collecting, obtaining or otherwise acquiring **ownership of or other property rights with respect to** genetic **materials** [resources.]

Note: We interpret this definition to apply only to access to physical items (i.e., plants, animals, microbes, etc.) and not to intangible subjects such as associated knowledge or traditional knowledge, innovations or practices. If there is uncertainty on this point, then we suggest the definition should be revised to state explicitly that the term genetic resources only means physical items.

Benefit-sharing

"Benefit-sharing" means, **in accordance with terms mutually agreed between the provider and the user, the exchange of monetary and/or non-monetary benefits arising from the scientific, commercial or other utilization of genetic resources for access to such genetic resources. These benefits may be provided prior to, at the time of, or following the granting of access. Benefits may include participation in research or compensation in the event of commercialization of a product involving the originally collected genetic materials.** [all forms of compensation for the utilization of genetic resources, whether monetary or non-monetary, and includes, in particular, the participation in scientific research and development on genetic resources, and the making available of the findings of such scientific research and development, and the transfer of technology.]

Commercialization

"Commercialization" **means, unless the provider and the user otherwise agree, the sale, lease or license on commercial terms to prospective purchasers, lessees or licensees of the products, technologies, results or benefits based on or arising from the genetic resources provided by the provider** [means making available genetic resources or the findings of research and development on such resources on commercial terms.] **Unless the provider and the user otherwise agree, the term "commercialization" does not refer to the publication or dissemination of the results, products and other information arising from research on the genetic resources provided by the provider.**

Legal Entity

"**Legal** Entity" means any [natural or] legal person **as defined by national legislation.** [or any plurality thereof; any community; any government or any body placed under its authority; or any organization, regardless of whether this organization is governmental or non-governmental.]

[IF NEEDED] *Ex situ* collection

"Ex situ collection" means a collection of genetic resources maintained outside their natural habitat. [Means any natural or legal person or plurality thereof; any community; any government or any body placed under its authority; or any organization, regardless of whether this organization is governmental or non-governmental.]

Provider

"Provider" means any **person or persons or any legal** entity which makes available genetic resources to users.

[IF NEEDED] Stakeholder

"Stakeholder" shall be determined on case-by-case basis by the government in accordance with national legislation, regulation and polices. In general, "stakeholders" may refer to a person or entity that is directly involved in or substantially and directly affected by the conservation or use of the genetic resources in question, which could include affected indigenous and local communities, healers, governments, private businesses and others. [Stakeholder means any entity which is involved in, or affected in its traditional use of genetic resources by, the collection or other acquisition of genetic resources, the utilization of theses resources and the sharing of benefits arising from their utilization.]

User

"User" means any **person or persons or any legal** entity which **seeks to collect, obtain or otherwise acquire genetic material for its genetic resources to explore the scientific, medical or commercial development potential or to supply such genetic material to a third person or entity.** [collects, obtains and otherwise acquires genetic resources to conduct scientific and development on these genetic resources, to commercialize the findings of this scientific research and development, or to supply other entities with these genetic resources.]

[IF NEEDED] Voluntary nature

An instrument of "voluntary nature" is not legally binding. [However, subscribing such an instrument may possibly have the consequence of being obliged to give reasons for deviating behavior.]

II. Other Approaches and Measures to Support Compliance with Prior Informed Consent

The U.S. Government has developed other approaches on access to genetic resources and benefit-sharing that are consistent with and complementary to the Bonn Guidelines. These measures are practical and are not overly burdensome in terms of time or costs. Further, these measures incorporate the concepts of prior informed consent and mutually agreed terms for access and benefit-sharing. As discussed below, these other approaches and measures include model contractual agreements and a model system for land stewards on access and benefit-sharing. The U.S. Government has also submitted much of this information to the World Intellectual Property Organization (WIPO), and the World Trade Organization (WTO). The United States is supportive of a review of other approaches and compliance measures for prior informed consent, including existing and proposed codes of conduct, model contractual agreements, model laws and indicators, to evaluate their appropriateness and likely impact on facilitating access to genetic resources and benefit-sharing.

A. Model Contractual Agreements

Two U.S. Government agencies have developed model contractual agreements for international access to genetic resources and benefit-sharing that may be of particular interest for the CBD: the National Cancer Institute, and the Agriculture Research Service the U.S. Department of Agriculture. These two agencies are currently using these agreements around the world. The text of the two agreements are attached and are also available on the WIPO website as **WIPO/GRTKF/IC/2/13** (December 12, 2001) "INFORMATION DOCUMENT ON CONTRACTUAL AGREEMENTS CONCERNING ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING".

1. National Cancer Institute

In general, the National Cancer Institute (NCI) seeks genetic resources of possible interest to cancer researchers. The NCI model contractual agreement operates as an agreement (either a Memorandum of Understanding or a Letter of Collection) between NCI and a foreign partner. Over two dozen foreign partners, from Latin America, Africa, Asia, Australia and Europe, have concluded such agreements with the NCI. This model is particularly noteworthy because of its use of a two-stage approach to benefit-sharing. In the first stage, the NCI collaborates with foreign partners in the exchange of results, the support of short-term and long-term visitors to discuss further collaboration and undertake training in drug discovery, respectively, and technology transfer. If, after analysis of genetic resources covered by the first stage an agreement, the NCI decides to proceed to the second stage of patenting the product of its research and seeks to license it for development and possible production and marketing, then it will require the licensee to return to the foreign partner to negotiate an agreement concerning royalties and other forms of compensation, as appropriate. Given how rarely this occurs, this two-stage approach makes sense. The parties conduct negotiations on monetary benefit-sharing only where there is a reasonable possibility of commercialization of a product and at a time when there is more information about the likely value of the product.

2. U.S. Department of Agriculture

The Agriculture Research Service (ARS) of the U.S. Department of Agriculture (USDA) administers one of the strongest national programs for conserving plant genetic resources and making them available for crop improvement and sustainable use. The USDA/ARS model contractual agreement is in the form of a Plant Exploration Proposal between USDA/ARS and the plant explorer. This agreement underscores the importance of collaborating with the host government scientists, helping to build the host government's capacity to conserve plant genetic resources, and sharing equitably the results of research results with the host government.

B. Model Access and Benefit-sharing System for Land Stewards - The National Park Service

The National Park Service (NPS) of the U.S. Department of the Interior has over a hundred years of experience in regulating access to protected areas. Researchers have shown great interest in the genetic resources found within national parks. In order to provide for prior informed consent and benefit-sharing, the NPS several years ago studied then existing systems around the world and sought expert advice on what land steward system it should employ for its Yellowstone National Park. The attached paper describes the system the NPS has been developing.

C. Governmental and Public Outreach

The U.S. Government has been actively engaged in informing U.S. scientists and U.S.-funded scientists, either working for the U.S. Government or academia or the private sector or otherwise, about the importance of obtaining prior informed consent and mutually agreed terms for obtaining access to genetic resources outside the United States and providing monetary and/or non-monetary benefit-sharing. The U.S. Government has been conveying this message at conferences, meetings and electronically through the Internet.

D. Guidelines

The United States believes that well-crafted guidelines can provide valuable assistance with respect to access to genetic resources and benefit-sharing. The U.S. Government has been supportive of the development and utilization of the Bonn Guidelines. The U.S. Government actively participated in the development of the UN Food and Agriculture Organization's International Code of Conduct for Plant Germplasm Collecting and Transfer, which the U.S. Department of Agriculture refers prospective collectors to in developing their plant exploration proposals.

The National Institutes of Health (NIH), USDA and the National Science Foundation (NSF) have sponsored the development of a grants program called the International Cooperative Biodiversity Groups to develop equitable models of pharmaceutical discovery and development based on biodiversity. In connection with this initiative, they have developed principles for accessing genetic resources, the treatment of intellectual property and the sharing of benefits associated with ICBG-sponsored research. These principles are incorporated in the contractual agreements used by the ICBG in carrying out its activities. These principles are attached.

III. Capacity-building to Implement the Bonn Guidelines

The U.S. Government has been a leader in capacity-building activities on access and benefit-sharing of genetic resources, especially in developing countries and countries with economies in transition. U.S. Government agencies for years have been carrying on a wide variety of such activities. A paper highlighting some of the many capacity-

building activities carried on by U.S. agencies and sources for obtaining additional information was submitted to the CBD's Open-ended Expert Workshop on Capacity-building for Access to Genetic Resources and Benefit-sharing, which took place in Montreal, Canada, December 2-4, 2002. This paper was included in Information Document UNEP/CBD/ABS/EW-CB/1/INF/2/ADD3 and is available on the CBD website.

Furthermore, the Tulalip Tribes, with support from the U.S. Department of the Interior, has carried out the *Cultural Stories* project. This project presents a model for developing and maintaining a traditional knowledge database with respect to the environment and genetic resources. *Cultural Stories* is both a concept and computer software. The concept is to efficiently manage the full range of information pertinent to tribes for the conservation of traditional knowledge and biodiversity, as well as to promote cultural survival. *Cultural Stories,* as computer software, has been developed by the Tulalip Tribes for free use by other tribes and indigenous communities. The software is a database program powered by the cost-free program ICONS which was refined as an electronic component of the *Cultural Stories* project. It operates in the Windows personal computer environment and functions on a stand alone and LAN basis. It is now being developed for network application on the world wide web. Wherever it is run, the principle is the same – local or indigenous community gathers data relevant to them and stores that data locally. Access is controlled by the indigenous or local community's managers of the software. *Cultural Stories* is a capacity building tool to support indigenous governance, sustainable development and cultural preservation to strengthen (or restore) a cultural landscape in the broadest possible context of the intangible and tangible. A background fact sheet on the Tulalip *Cultural Stories* Project is attached.

ATTACHMENTS:

1. The National Cancer Institute Memorandum of Understanding
2. The National Cancer Institute Letter of Collection
3. The Agriculture Research Service of the U.S. Department of Agriculture
   Guidelines for Plant Exploration Proposal
4. The National Park Service of the U.S. Department of the Interior
   Application Procedures and Requirements for Scientific
   Research And Collecting Permits
5. The Principles for Accessing Genetic Resources, the Treatment Of Intellectual
   Property and the Sharing Of Benefits Associated With ICBG-Sponsored
   Research
6. Background on the Tulalip Cultural Stories Project

MEMORANDUM OF UNDERSTANDING BETWEEN [SOURCE COUNTRY ORGANIZATION] AND THE DEVELOPMENTAL THERAPEUTICS PROGRAM DIVISION OF CANCER TREATMENT AND DIAGNOSIS NATIONAL CANCER INSTITUTE

The Developmental Therapeutics Program (DTP), Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI) is currently screening synthetic compounds and natural product materials derived from plants, marine macro-organisms and microbes as potential sources of novel anticancer drugs. The DTP is the drug discovery program of the NCI which is an Institute of the National Institutes of Health (NIH), an arm of the Department of Health and Human Services of the United States Government. While investigating the potential of natural products in drug discovery and development, NCI wishes to promote the conservation of biological diversity, and recognizes the need to compensate source country organizations and peoples in the event of commercialization of a drug developed from an organism collected within their countries' borders.

DTP/NCI has an interest in investigating plants, terrestrial and marine microorganisms and marine macro-organisms from [Source Country], and wishes to collaborate with the [Source Country Organization ("SCO")] in this investigation. DTP/NCI will make sincere efforts to transfer knowledge, expertise, and technology related to drug discovery and development to [SCO] in [Source Country] (as the agent appointed by the [Source Country] Government), subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology. [SCO], in turn, desires to collaborate closely with the DTP/NCI in pursuit of the investigation of [Source Country]'s terrestrial plants, marine macro-organisms and microorganisms, and selected synthetic compounds subject to the following conditions and stipulations of this Memorandum of Understanding (MOU).

1). On the basis of in-house screening results in its anticancer screens, [SCO] may select both synthetic compounds and extracts of plants, marine macro-organisms and microorganisms (subject to previously determined limits as to numbers per year) for anticancer testing at DTP/NCI. If suitable in-house screens are not available, a list of available materials may be sent to DTP/NCI giving data as requested in Articles 2 and 3 below.

2). Prior to submission of the materials, [SCO] will send a data sheet, to be held in confidence by DTP/NCI, on each material so that DTP/NCI may check its databases for records of prior submission to DTP/NCI.

3). For pure compounds, the data sheet(s) will give pertinent available data as to chemical constitution, structure, biological data, solubility, toxicity and any precautions which need to be followed in handling, storage and shipping.

For crude extracts, data will be provided as to the source organism taxonomy, location and date of collection, any hazards associated with the organism, available biological data and any known medicinal uses of the organism/extracts.

4). DTP will inform [SCO] which of the materials are new to the program, and such materials will be shipped to DTP for screening. DTP will provide a record of the accession number for the materials. Quantities of materials required for initial testing are 5 mg for pure compounds and 10 mg for crude extracts.

5). All test results will be provided to [SCO] as soon as they are available, but not later than 270 days (nine months) from the date of receipt of the sample. If available, *in vitro* test results will be delivered within 90 days from receipt of the sample. [SCO] will be informed in writing of any delays beyond this period (270 days) together with an explanation of the reason(s) for delay.

Data provided by [SCO] will be considered as confidential information of [SCO], if so labeled, and will be held confidentially by DTP/NCI, unless the data are already in the public domain. No data about the materials will be kept in files open to the public either by DTP/NCI, testing laboratories, or data processing facilities, all of which are U.S. government contractors. Only those employees directly engaged in the operation of DTP/NCI will have access to the files of information regarding the source and nature of confidential materials and results of testing, unless the release of data about the materials or the results of the testing are required under statute or by court order.

6). Any extracts exhibiting significant activity will be further studied by bioassay-guided fractionation in order to isolate the pure compound(s) responsible for the observed activity. Such fractionation will be carried out in [SCO] laboratories. If [SCO] has no available bioassay, DTP/NCI will assist [SCO] to establish the necessary bioassay systems subject to the availability of the necessary resources. Alternatively, or in addition, suitably qualified designated [SCO] scientists will be sent to DTP/NCI for the isolation studies subject to the terms stated below in Article 7. In addition, during the course of this MOU, DTP/NCI will assist the [SCO], thereby assisting the [SC], to develop the capacity to undertake drug discovery and development, including capabilities for the screening and isolation of active compounds from terrestrial and marine organisms.

7). Subject to the provision that suitable laboratory space and other necessary resources are available, DTP/NCI agrees to invite senior technician(s) and/or scientist(s) designated by [SCO] to work in the laboratories of DTP/NCI or, if the parties agree, in laboratories using technology which would be useful in furthering

work under this MOU. The duration of such visits would not exceed one year except by prior agreement between [SCO] and DTP/NCI. The designated "Visiting Scientist(s)" will be subject to provisions usually governing Guest Researchers at NIH, except when carrying out research on materials provided by [SCO]. Costs and other conditions of visits will be negotiated in good faith prior to the arrival of the scientist(s).

8). In the event that an agent isolated and purified from materials provided by [SCO], and/or a synthetic compound provided by [SCO] meets the criteria established by the Drug Development Group (DDG) of NCI's DCTD (DTP's parent organization), which would include, but not be limited to, *in vivo* activity in rodent models, further development of the agent will be undertaken by DTP/NCI in collaboration with [SCO]. Once an active agent is approved by DTP/NCI for preclinical development (*i.e.*, has passed the DDG at Stage IIA), DTP/NCI will collaborate with [SCO] scientists in the development of the specific agent.

9). Both [SCO] and DTP/NCI recognize that inventorship will be determined under patent law. DTP/NCI and [SCO] will, as appropriate, jointly seek patent protection on all inventions developed jointly under this MOU by DTP/NCI and [SCO] employees, and will seek appropriate protection abroad, including in [Source Country], if appropriate. Application for patent protection on inventions made by [SCO] employees alone will be the responsibility of [SCO]. Application for patent protection on inventions made by DTP/NCI employees alone will be the responsibility of DTP/NCI.

With respect only to those compounds that have been determined to possess such significant anti-cancer potential as to be scheduled for clinical trials by DCTD, the U.S. Government shall have a royalty-free, irrevocable, nonexclusive license to manufacture and/or use by or for the U.S. Government the invention(s) claimed in any patents that [SCO] may have or may obtain on such compounds or on a process for use of such compounds. However, this license will apply only to [SCO] patents that rely upon data generated by DTP/NCI or DTP/NCI testing laboratories. This license shall be only for medical research purposes related to or connected with the therapy of cancer. The term "medical research purposes" as used herein shall not include treatment of patients outside of clinical trials or commercial distribution of the compounds.

10). DTP/NCI will make a sincere effort to transfer any knowledge, expertise, and technology developed during such collaboration in the discovery and development process to [SCO], subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology.

11). All licenses granted on any patents arising from the collaboration conducted under

the terms of this MOU shall contain a clause referring to this MOU and shall indicate that the licensee has been apprised of this MOU.

12). Should the agent eventually be licensed to a pharmaceutical company for production and marketing, DTP/NCI will require the licensee to negotiate and enter into agreement(s) with [SCO] and/or an appropriate [Source Country] Government agency(ies). The agreement(s) will address the concern on the part of the [Source Country] government that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate.

Such terms will apply equally to instances where an invention is directed to a direct isolate from a natural product material, a product structurally based upon an isolate from the natural product material, a synthetic material for which the natural product material provided a key development lead, a derivative of a synthetic compound provided by [Source Country] or [SCO], or a method of synthesis or use of any aforementioned isolate, product, material or derivative; though the percentage of royalties negotiated as payment might vary depending upon the relationship of the marketed drug to the originally isolated product. It is understood that the eventual development of a drug to the stage of marketing is a long term process which may require 10-15 years.

13). In obtaining licensees, DTP/NCI will require the applicant for license to seek as its first source of supply the natural products available from [Source Country]. If no appropriate licensee is found who will use natural products available from [Source Country], or if [SCO] or their suppliers cannot provide adequate quantities of raw materials at a mutually agreeable fair price, the licensee will be required to pay to the [Source Country] Government an amount of money (to be negotiated) to be used for expenses associated with cultivation of medicinal plant species that are endangered by deforestation, or for other appropriate conservation measures. These terms will also apply in the event that the licensee begins to market a synthetic material for which a material from [Source Country] provided a key development lead.

14) Article 13 shall not apply to organisms which are freely available from different countries (i.e., common weeds, agricultural crops, ornamental plants, fouling organisms) unless information indicating a particular use of the organism (e.g., medicinal, pesticidal) was provided by local residents to guide the collection of such an organism from [Source Country], or unless other justification acceptable to both [SCO] and DTP/NCI is provided. In the case where an organism is freely available from different countries, but a phenotype producing an active agent is found only in [Source Country], Article 13 shall apply.

15). Publication of data resulting from the collaboration under this MOU will be

undertaken at times determined by an agreement between [SCO] and DTP/NCI.

16). It is the intention of NCI that [SCO] not be liable to DTP/NCI for any claims or damages arising from NCI's use of the material provided by [SCO]; however, no indemnification for any loss, damage, or liability is intended or provided by any party under this MOU. Each party shall be liable for any loss, claim, damage or liability, that said party incurs, as a result of said party's activities under this MOU, except that the NCI, as an agency of the United States, assumes liability only to the extent as provided under the Federal Tort Claim Act (28 U.S.C. § 171).

17) DTP/NCI will not distribute materials provided by [SCO] to other organizations without written authorization from [SCO]. However, should [SCO] wish to consider collaboration with organizations selected by NCI for distribution of materials acquired through NCI collection contracts, DTP/NCI will establish contact between such organizations and [SCO].

18). [SCO] scientists and their collaborators may screen additional samples of the same materials for other biological activities and develop them for such purposes independently of this MOU.

This MOU shall be valid as of the date of the final authorized signature below for an initial period of five (5) years, after which, it can be renewed by mutual agreement. It may be amended at any time subject to the written agreement of both parties. Copies of such amendments will be kept on file at both of the addresses indicated below. [SCO] and DTP/NCI are confident that this MOU will lay the basis for a mutually successful cooperation in discovering and developing new therapies in the treatment of cancer.

For the [SCO]:

_____

_____
Date

mailing and contact address:

For the National Cancer Institute:

_____

National Cancer Institute

_____
Date

mailing and contact address:

Technology Transfer Branch

National Cancer Institute at Frederick
NCI-Frederick
Fairview Center, Suite 502
1003 - W. 7th Street
Frederick, MD 21701-8512

LETTER OF COLLECTION

Agreement Between
[Source Country Organization]
and the
Developmental Therapeutics Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute

The Developmental Therapeutics Program (DTP), Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI) is currently investigating plants, microbes, and marine macro-organisms as potential sources of novel anticancer drugs. The DTP is the drug discovery program of the NCI which is an Institute of the National Institutes of Health (NIH), an arm of the Department of Health and Human Services of the United States Government. While investigating the potential of natural products in drug discovery and development, NCI wishes to promote the conservation of biological diversity, and recognizes the need to compensate supplier organizations and peoples in the event of commercialization of a drug developed from an organism collected within their borders.

As part of the drug discovery program, DTP has contracts with various organizations for the collection of plants, microbes and marine macro-organisms worldwide. DTP has an interest in investigating plants, microbes and marine macro-organisms from the [Source Country], and wishes to collaborate with the [Source Country Government (SCG) or Source Country Organization(s) (SCO)], as appropriate, in this investigation. The collection of plants, microbes and marine macro-organisms will be within the framework of the collection contract between the NCI and the NCI Contractor (Contractor) which will collaborate with the appropriate agency in the [SCG or SCO]. The NCI will make sincere efforts to transfer knowledge, expertise and technology related to drug discovery and development to the appropriate [Source Country Institution (SCI)] in [[Source Country] as the agent appointed by the [SCG or SCO], subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology. The [SCG or SCO], in turn, desires to collaborate closely with the DTP/NCI in pursuit of the investigation of plants subject to the conditions and stipulations of this agreement.

The role of DTP, DCTD, NCI in the collaboration will include the following:

1) DTP/NCI will screen the extracts of all plants provided from [Source Country] for anticancer activity, and will provide the test results to [SCI] on a quarterly basis. Such results will be channeled via Contractor.

2) The test results will be kept confidential by all parties, with any publication delayed until DTP/NCI has an opportunity to file a patent application in the United States of America on any active agents isolated. Such application will be made according to the terms stated in Article 6.

3) Any extracts exhibiting significant activity will be further studied by bioassay-guided fractionation in order to isolate the pure compounds(s) responsible for the observed activity. Since the relevant bioassays are only available at DTP/NCI, such fractionation will be carried out in DTP/NCI laboratories or laboratories approved by DTP/NCI. A suitable qualified scientist designated by [SCI] may participate in the process subject to the terms stated in Article 4. In addition, in the course of the contract period, DTP/NCI will assist [SCG or SCO], in conjunction with [SCI], to develop the capacity to undertake drug discovery and development, including capabilities for the screening and isolation of active compounds from plants, microbes and marine organisms.

4) Subject to the provision that suitable laboratory space and other necessary resources are available, DTP/NCI agrees to invite a senior technician or scientist designated by [SCI] to work in laboratories of DTP/NCI or, if the parties agree, in laboratories using technology which could be useful in furthering work under this agreement. The duration of such a visit would not exceed one year except by prior agreement between [SCI] and DTP/NCI. The designated Guest Researcher will be subject to provisions usually governing Guest Researchers at NIH, except when carrying out research on materials provided through collections in [Source Country]. Salary and other conditions of exchange will be negotiated in good faith.

5) In the event of the isolation of a promising agent from a plant, microbe or marine macro-organism collected [Source Country], further development of the agent will be undertaken by DTP/NCI in collaboration with [SCI]. Once an active agent is approved by the DTP/NCI for preclinical development, [SCI] and the DTP/NCI will discuss participation by SCI scientists in the development of the specific agent.

The DTP/NCI will make a sincere effort to transfer any knowledge, expertise, and technology developed during such collaboration in the discovery and development process to [SCI], subject to

the provision of mutually acceptable guarantees for the protection of intellectual property associated with patented technology.

6) DTP/NCI will, as appropriate, seek patent protection on all inventions developed under this agreement by DTP/NCI employees alone or by DTP/NCI and [SCG or SCO] employees jointly, and will seek appropriate protection abroad, including in [Source Country], if appropriate.

7) All licenses granted on any patents arising from this collaboration shall contain a clause referring to this agreement and shall indicate that the licensee has been apprised of this agreement.

8) Should the agent eventually be licensed to a pharmaceutical company for production and marketing, DTP/NCI, will require the successful licensee to negotiate and enter into agreement(s) with the [SCG] agency(ies) or [SCO] as appropriate. This agreement(s) will address the concern on the part of the [SCG or SCO] that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate.

9) Such terms shall apply equally to instances where an invention is directed to a direct isolate from a natural product material, a product structurally based upon an isolate from the natural product material, a synthetic material for which the natural product material provided a key development lead, or a method of synthesis or use of any aforementioned isolate, product or material; though the percentage of royalties negotiated as payment might vary depending upon the relationship of the marketed drug to the originally isolated product. It is understood that the eventual development of a drug to the stage of marketing is a long term process which may require 10-15 years.

10) In obtaining licensees, the DTP/NCI will require the license applicant to seek as its first source of supply the natural products from [Source Country]. If no appropriate licensee is found that will use natural products available from [Source Country], or if the [SCG] or [SCO], as appropriate, or its suppliers cannot provide adequate amounts of raw materials at a mutually agreeable fair price, the licensee will be required to pay the [SCG] or [SCO], as appropriate, an amount of money (to be negotiated) to be used for expenses associated with cultivation of medicinal plant species that are endangered by deforestation, or for other appropriate conservation measures. These terms will also apply in the event that the licensee begins to market a synthetic material for which a material from [Source Country] provided a key development lead.

11) Section 10 shall not apply to organisms which are freely available from different sources (i.e., common weeds, agricultural crops, ornamental plants, fouling organisms) unless information indicating a particular use of the organism (e.g., medicinal, pesticidal) was provided to guide the collection of such an organism from [source Country], or unless other justification acceptable to both the [SCG or SCO] and the DTP/NCI is provided. In the case where an organism is freely available from different sources, but a phenotype producing an active agent is found only in [Source Country], Article 10 shall apply.

12) DTP/NCI will test any pure compounds submitted by the [SCG or SCO] and [SCI] scientists for antitumor activity, provided such compounds have not been tested previously in the DTP/NCI screens. If significant antitumor activity is detected, further development of the compound and investigation of patent rights will, as appropriate, be undertaken by DTP/NCI in consultation with [SCI] and the [SCG or SCO].

Should an agent derived from the compound eventually be licensed to a pharmaceutical company for production and marketing, DTP/NCI will require the successful licensee to negotiate and enter into agreement(s) with the appropriate [SCG agency(ies) or SCO]. This agreement will address the concern on the part of the [SCG or SCO] that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate.

13) DTP/NCI may send selected samples to other organizations for investigation of their anti-cancer, anti-HIV or other therapeutic potential. Such samples will be restricted to those collected by NCI contractors unless specifically authorized by [SCG or SCO]. Any organization receiving samples must agree to compensate the [SCG or SCO] and individuals, as appropriate, in the same fashion as described in Articles 8-10 above, notwithstanding anything to the contrary in Section 11.

The role of the Source Country Government (SCG) or Source Country Organization(s) (SCO) in the collaboration will include the following:

1) The appropriate agency in [SCG or SCO] will collaborate with Contractor in the collection of plants, microbes and marine macro-organisms, and will work with Contractor to arrange the necessary permits to ensure the timely collection and shipment of materials to DTP/NCI.

2) Should the appropriate agency in [SCG or SCO] have any knowledge of the medicinal use of any plants, microbes and marine macro-organisms by the local population or traditional healers, this information will be used to guide the collection of plants, microbes or marine macro-organisms on a priority basis where possible. Details of the methods of administration (e.g., hot infusion, etc.) used by the traditional healers will be provided where applicable to enable suitable extracts to be made. All such information will be kept confidential by DTP/NCI until both parties agree to publication.

The permission of the traditional healer or community will be sought before publication of their information, and proper acknowledgment will be made of their contribution.

3) The appropriate agency in [SCG or SCO] and Contractor will collaborate in the provision of further quantities of active raw material if required for development studies.

4) In the event of large amounts of raw material being required for production, the appropriate agency of the [SCG or SCO] and Contractor will investigate the mass propagation of the material in the [Source Country]. Consideration should also be given to sustainable harvest of the material while conserving the biological diversity of the region, and involvement of the local population in the planning and implementation stages.

5) [SCG or SCO] and SCI scientists and their collaborators may screen additional samples of the same raw materials for other biological activities and develop them for such purposes independently of this agreement.

This agreement shall be valid as of the date of the final authorized signature below for an initial period of five (5) years, after which it can be renewed by mutual agreement. It may be amended at any time subject to the written agreement of both parties. Copies of such amendments will be kept on file at both of the addresses indicated below.

For the National Cancer Institute

_____

National Cancer Institute

For [SCI] or [SCO]

_____

Name (typed):

Title:

Date

Mailing and contact address:

Technology Development Branch
National Cancer Institute at Frederick
(NCI-Frederick)
Fairview Center, Suite 502
1003 W. 7th Street
Frederick, MD21701-8512
U.S.A.

Date

Mailing and contact address:

National Germplasm Resources Laboratory
USDA/ARS, Beltsville, Maryland

FY2002 GUIDELINES FOR PLANT EXPLORATION PROPOSALS

The United States Department of Agriculture (USDA), Agricultural Research Service (ARS) funds foreign and domestic plant explorations to acquire plant germplasm for inclusion in the U.S. National Plant Germplasm System. Plant exploration proposals must be supported by the appropriate Crop Germplasm Committee (CGC), or other qualified crop specialists when there is no appropriate CGC, Proposals are recommended for funding by the Plant Germplasm Operations Committee (PGOC) and approved by the ARS National Program Staff. Plant Exploration Proposals may be submitted by any qualified scientist. The Guidelines presented here are for proposals to be funded during the period October 1, 2001 - September 30, 2002 (Fiscal Year 2002); previous versions are obsolete. The Guidelines for Plant Exploration Proposals are revised annually and may be obtained from the Plant Exchange Office (PEO), Beltsville, Maryland.

The format for plant exploration proposals is designed to guide prospective explorers through the necessary background study required to obtain the information necessary for sound planning and effective implementation of field programs, to fully inform reviewers, and to provide a basis for judging and prioritizing proposals. The format for the project summary (Attachment A) is designed to comply with ARS Directive 281.1 (Extramural Research-Grant Agreements) so that grants can be used to fund explorations by non-ARS scientists. The policy of the PEO is not to provide funds to cover institutional overhead. When ARS funds an exploration by a non-ARS employee, the exploration is considered to be in the mutual interest of that person's institution and ARS, and a waiver of overhead is warranted. The format requires that the grantee certify that overhead will be waived. The format also requires certification that the collector will provide complete "passport" data, including latitude and longitude, for each collection.

Scientists planning to submit a proposal are advised to first consult Karen Williams in the PEO. The PEO can provide suggestions and assistance with technical matters when preparing a proposal. Participants on foreign ARS-supported explorations are required to follow the Guidelines for Conduct of Foreign Plant Explorations (Attachment B). Participants should also be aware of the voluntary FAO Code of Conduct for Plant Germplasm Collecting and Transfer, copies of which may be obtained from PEO upon request. Explorations must be made in compliance with the host country's laws governing access to germplasm. Regulations in different countries vary significantly. Permission for access to germplasm must be obtained from the host country authority designated by the national government. Permission may also be required by regional, state or individual landholding authorities. Scientists submitting proposals are strongly encouraged to consult with the PEO regarding access issues. The PEO often assists with communicating about access issues with host country governments, and

agreements governing access to germplasm are negotiated by the PEO.

Laws in some countries require benefit-sharing beyond that routinely associated with plant explorations in order to obtain access to plant genetic resources. Depending on the situation in the host country, a limited amount of funds may be requested in the budget for additional non-monetary benefits. These expenditures should increase the country's capacity to conserve plant genetic resources and may include supplies, training of host country scientists, and workshops conducted by exploration participants. The host country authority for access will determine the acceptability of the non-monetary benefits. Please consult with the PEO before including benefits of this type in your proposal.

All germplasm obtained from ARS-funded plant explorations is added to the National Plant Germplasm System (NPGS) where it will be curated, evaluated and made available for distribution. Germplasm in the NPGS is available to all bona fide users, public, private and foreign. Germplasm collected on ARS-funded explorations will be distributed to non-NPGS participants after deposition in the NPGS, and will be subject to the conditions of any agreements signed with the host country.

The prevention of accidental introduction of noxious weeds, insects, diseases and other organisms into the United States is of utmost concern to ARS. Participants on ARS-supported explorations are required to closely follow U.S. plant quarantine laws and regulations administered through the USDA Animal and Plant Health Inspection Service (APHIS). Participants must declare all germplasm upon their return to the U.S. The germplasm should be inspected by an APHIS inspector for evidence of insects, disease or weed contamination and treated appropriately, when necessary.

A separate proposal format entitled "Guidelines for Germplasm Exchange Proposals" is available from the PEO for proposals involving expeditions to exchange germplasm with foreign genebanks when the expedition plans do not include exploration.

Preparation of proposal: The format for preparing proposals is outlined in Attachment A. For specific advice on proposal items 19 and 20, consult Maryann Loftus (Telephone: 301-504-5020; Email: mloftus@ars-grin.gov) of the PEO. Request a written endorsement for the proposal from the appropriate Crop Germplasm Committee (CGC), or other qualified crop specialists when there is no appropriate CGC. The NPGS curator(s) responsible for the proposed collections must sign a statement (see item 20) to certify that they anticipate having the capacity to curate the collections.

Draft proposal: Because the assistance of PEO is frequently required in acquiring host country approvals for explorations, please submit a draft proposal to the PEO by April 15, 2001. The draft should include items 1, 2, 3, 4, 5, 6, and 7 (brief explanation of need). Early notification will allow the PEO to assist with meeting host country requirements for access to germplasm and with negotiating terms.

Final submission of proposals: Submit the proposal to the PEO **no later than July 1, 2001**. This deadline may be waived to permit response to real emergencies.

Review of proposals: Proposals are reviewed by a committee composed of members of the Plant Germplasm Operations Committee (PGOC) and a representative of each of the four NPGS Regional Technical Committees. CGC recommendations are considered by the committee when it reviews proposals for funding. The committee prioritizes acceptable proposals and recommends these for approval by the ARS Administrator.

Notification of funding decision: Scientists will be notified in writing by PEO of the decision regarding funding of their proposal. This notification may occur as late as December, 2001. Scientists whose explorations are funded will receive instructions on funding arrangements, a checklist for requirements, and the FAO report forms for assessment of genetic erosion in natural habitats. If evidence of genetic erosion is observed in the field, an FAO report form should be completed in collaboration with host country scientists and submitted to FAO by the host country government. The FAO report forms for assessment of genetic erosion of wild crop relatives is available on the Internet at http://apps2.fao.org/wiews/ews_part2.thtml. The FAO report form for assessment of genetic erosion of local varieties is available on the Internet at http://apps2.fao.org/wiews/ews_part3.thtml.

Documentation requirements: Each collection must be documented with sufficient data. A sample data collection sheet is attached (Attachment C). Explorers are urged to develop their own similar data collection formats tailored to the target crop species. The PEO can provide help in modifying or preparing data collections forms for specific expeditions.

It is important that collectors carefully record locality data (including latitude, longitude, and elevation), associated vegetation, habitat description, plant characteristics and local uses of the plant for all germplasm. Use of Global Positioning System (GPS) devices for determining accurate longitude and latitude and altimeters for accurate altitude is required. Such devices are available on loan from the PEO. A copy of the data should accompany all germplasm sent to the USDA Plant Germplasm Quarantine Center (Bldg. 580, BARC-East, Beltsville, MD 20705).

Collectors are requested to use a identification system for germplasm samples that combines characters and numbers. Characters can refer to the collectors' initials, the country in which the exploration is conducted, or the species collected. This will greatly facilitate the tracking of accessions in the Germplasm Resources Information Network (GRIN) database.
A herbarium voucher specimen should be prepared for any collection which cannot be identified authoritatively in the field, for a collection which possesses uncharacteristic morphological traits, and especially for all collections of wild relatives of crop plants. At least one duplicate herbarium voucher should be deposited in an internationally recognized herbarium. It is recommended that voucher specimens of woody landscape species be deposited with the U.S. National Arboretum Herbarium.

Reporting requirements: Within 30 days of completion of the exploration, a summary report (see Attachment D for format) must be submitted to the PEO. Within 60 days of completion of the exploration, a final report is required. **Future exploration proposals by the same participants will not be approved for funding until the final report is received.**

The final report should include:

a. Catalog of collections: a record of all collections including all passport data. This may be in electronic form.

b. Narrative report: 3 to 5 single-spaced pages (more, if necessary). Include significant observations likely to be of interest to germplasm users, or other explorers who may visit the same areas in the future. Provide a list of contacts (domestic and foreign) with complete addresses and indicate how they contributed to the mission and how they might contribute to future missions in the same country.

c. Page-size map showing itinerary: identify principal points on the itinerary and most important collection sites.

d. Information on any threats to genetic resources in the area visited.

ARS scientists: ARS scientists are required to follow USDA and ARS regulations in obtaining travel authorization, implementing travel, accounting for expenses and submitting a trip report.

Requests for further information and plant exploration proposals should be directed to:

Plant Exchange Office
National Germplasm Resources Laboratory
Rm. 402, Bldg. 003, BARC-West
Beltsville, MD 20705-2350

PLANT EXPLORATION PROPOSAL FORMAT

The proposal must have a cover page with project title and summary. The following is an example and should be modified as appropriate.

PROJECT TITLE: PLANT EXPLORATION IN [NAME OF STATE(S)/COUNTRY(S] TO COLLECT [NAME OF CROP] GERMPLASM FOR CROP IMPROVEMENT.

PROJECT SUMMARY

The [name of Crop Germplasm Committee (CGC), or if no appropriate CGC, name of crop specialist] has determined there is a need for additional [name of crop] germplasm from [state(s)/country(s)]. This germplasm is desired for breeding programs for crop improvement, does not exist in other germplasm collections and can only be obtained by collection. Additionally, [list specific threats] threaten its continued existence if not placed in an *ex situ* collection. Explorations will be made in compliance with [name of country(ies)]'s laws governing foreign access to germplasm. After being deposited in a designated genebank in [country], samples of the germplasm will be incorporated into the National Plant Germplasm System where it will be curated on behalf of the U.S. Government and will be available to all qualified scientists/organizations, domestic and foreign, who are eligible to receive it. Germplasm will be collected as seeds, bulbs, cuttings, or other propagules. When possible, collections will be documented with voucher herbarium specimens. All collections will be documented with complete "passport" data (description, locality of collection, including latitude and longitude, etc.). All germplasm will be shipped or carried to the USDA Plant Germplasm Quarantine Center, Beltsville, Maryland, from which it will be distributed according to policies in effect at time of receipt.

CERTIFICATION

(The leader of each exploration must sign on the signature line of section 1 below. Non-ARS participants must also sign on the signature line of section 2.)

1. For foreign plant explorations, I certify that I have read and will abide by the Guidelines for Conduct of Foreign Plant Explorations. I agree to abide by all rules and regulations of host countries concerning collection of plant genetic resources and understand that proper permission is required in advance of collection.

   I will **promptly** comply with reporting requirements explained in the Guidelines for Plant Exploration Proposals. I will provide a summary report, a narrative report, information on genetic erosion in the region visited and a catalog of collections. The catalog will include collector's name and number, plant name, collection locality, **including latitude, longitude and elevation**, and **appropriate descriptive information** (of plant and environment), etc.

   I understand that all germplasm obtained from ARS-funded plant explorations will be added to the National Plant Germplasm System (NPGS) where it will be curated on behalf of the U.S. Government.

   _____ _____
   Signature Date

2. As a non-ARS employee, I agree to the above and certify that I have consulted the appropriate official of my institution who has agreed to waive overhead.

   _____ _____
   Signature Date

1. Submitted by:
[Name, title, full address, telephone number, fax, and email.]

2. Objectives:
   a. Taxa to be collected:
   b. Specific or general characteristics sought:
   c. Use to be made of germplasm collected:

3. Dates of travel:
[Specify dates and briefly explain why this period is appropriate.]

4. Host country(s) or state(s):
[If proposal is for collecting in a foreign country indicate, as specifically as possible, the part of that country that will be visited (i.e., section of the country, states, provinces).]

5. Suggested participants:
[Identify each suggested participant and explain their qualifications including foreign language capabilities and previous foreign travel experience. If this proposal is for exploration in a foreign area, show date and place of birth and passport number for each suggested participant. The inclusion of more than two U.S. scientists requires justification.]

6. Host country (or state(s) or other) requirements to obtain collection permit and permit for export of germplasm:
[For foreign plant explorations, the appropriate procedure for obtaining access to plant genetic resources varies widely among countries. The PEO will assist in identifying host country authorities for access to germplasm. Depending on the regulations in the host country, the PEO may assume responsibility for communicating with host country authorities regarding access. Documentation of host country approval for the exploration will be required before funding is provided. In this section of the proposal, identify the authority in the host country, describe requirements (such as application forms) for obtaining permission for collection of germplasm, and give details on any progress made in requesting and obtaining permits.
For domestic plant explorations, plant collection permits must be obtained from landholders, both public and private. Landholding agencies, including federal agencies such as the National Park Service, may require considerable time for processing applications.]

7. Justification:
[Explain the need for collection and why the proposed field collection area will meet that need. Consider the abundance and distribution of the species to be collected; append distribution maps showing their known distribution. Statements on genetic erosion should be documented. The appropriate Crop Germplasm Committee should have identified the target germplasm as a priority for acquisition. Note any political factors which may have an impact on the

exploration, especially with reference to accessibility of field areas. Limit this section to three pages or less.]

8. Germplasm currently available:
[What germplasm of the species to be collected is now available in U.S. or foreign collections from the proposed field area? Has the Germplasm Resources Information Network (http://www.ars-grin.gov) been consulted?

9. How does the exploration relate to earlier explorations or subsequent expeditions?
[Discuss previous explorations for the same or related species in the proposed area of exploration. PEO can provide information on prior NPGS-supported explorations. Explain any future plans for exploration for the same or related species.]

10. CGC or other concurrence:
[Attach a copy of a letter from the appropriate CGC endorsing this exploration. If the target species are not covered by a CGC, letters from other specialists may be substituted. If the exploration is proposed in response to a CGC or other recommendation, so indicate.]

11. Benefits to host country:
[In this section, discuss both routine benefits that the host country will receive as a result of the exploration and any additional non-monetary benefits that are requested. Routine benefits include strengthened professional ties, transfer of information and technology, and conservation of native germplasm in the host country. Additional non-monetary benefits are discussed in paragraph 2 on page 2 of these guidelines. Omit this section for domestic exploration.]

12. Status of mapping and map requirements:
[What useful maps, especially road maps and topographic maps, are available? Which have been consulted?]

13. Vehicle and fuel requirements, availability, and cost:
[What type of vehicle will be needed in view of road conditions likely to be encountered, distances to be traveled, and persons and supplies to be transported? Will 4-wheel drive be required? Where will the vehicle be obtained; what will it cost to rent; what is the cost of gasoline? Is gasoline readily available in remote areas?]

14. Currency/exchange rates:
[Omit this section from proposal for domestic exploration.]

15. Holidays:
[American embassies honor local as well as U.S. holidays. Traveler should be aware of foreign holidays and, if possible, should avoid travel immediately before, during, and after major holidays. Omit this section for domestic exploration.]

16. Supplies and equipment:
    To be shipped or carried from U.S.:
        By participant(s):
        By Plant Exchange Office:
    To be obtained in host country:

    [Omit these details from proposal for domestic exploration, but indicate any supplies and equipment to be provided by PEO.]

17. Field plan:
    [How will collector(s) proceed after arrival in the field area? Will a reconnaissance be conducted before collection of germplasm? If the field party includes more than one person, will they travel together or independently? If independently, what will be the objectives of each? Will the entire itinerary be covered by motor vehicle? If not, to what extent, where, and for how long a period will travel by boat, foot, horse, helicopter, etc., be required? Consider condition of roads and physical accessibility of target areas, availability of food and lodging, etc. If international borders must be crossed (other than by air) address the feasibility of crossing such borders.]

18. APHIS requirements for import of germplasm:
    [Proposal should reflect contact with the USDA APHIS Plant Protection and Quarantine Permit Unit, Riverdale, Maryland regarding any quarantine restrictions and prohibitions for the taxa to be collected. Consulting the APHIS website (http://www.aphis.usda.gov/ppq/ss/permits/products/indes.shtml) is recommended. Omit this section for domestic exploration.]

19. How collections will be shipped to U.S. or other destination:
    [Explain how collections will be packed and shipped. If the collector plans to bring the germplasm from abroad to the U.S. by hand or as a part of his/her baggage, authorization from APHIS is required. Omit this section for domestic exploration.]

20. Disposition of germplasm after collection:
    [For all foreign explorations, proposal should reflect contact with the appropriate crop curator(s) and the appropriate contact in the Plant Germplasm Quarantine Office for explorations resulting in the introduction of germplasm that must be quarantined. Note any special distribution arrangements made for quarantine, propagation, or increase. For domestic collections, work out distribution arrangements with the appropriate crop curator(s). Have the curator(s) sign the Crop Curator Statement (Attachment A, page 7) to certify that they anticipate having the capacity to curate the collections. Include this statement with your proposal.]
21. Contacts and cooperators:
    [Provide name, title, address, etc. for each and indicate how they have contributed or will contribute to the success of the mission.]

22. References consulted:
[If personal communications are cited, attach copy.]

23. Itinerary (in target area):
[Show enough major points on the itinerary and distances between them in kilometers or miles to permit a determination as to whether there will be sufficient time for transit and collecting. Provide an outline map showing the general itinerary. If any side trips from the itinerary are planned by foot, horse, boat, etc., indicate approximate amount of time allowed for each.]

[NOTE: Begin Item 24 on a new page.]

24. Budget estimate:
[Show best estimate of cost for each participant for each budget item (air fare, excess baggage, per diem, vehicle rental, gasoline, driver, interpreter, supplies, etc.) for which the cost is $100 or more. For per diem, do not exceed official U.S. government rates. Salaries of participating scientists cannot be included. Indicate all sources of funds (USDA, State, or other).]

25. Attach vitae:
[Vitae are required to comply with the following requirement of Directive 281.1. "Vitae of key personnel to include principal investigator(s), senior associate(s), and other senior professionals should be provided in order to assist evaluators to assess the competence and experience of the project staff." Limit publications to the last five years.]

CROP CURATOR STATEMENT

I have been in contact with [fill in explorer's name] concerning the planned plant exploration to [fill in country or region]. I expect to have the capacity to curate the collections anticipated from this exploration.

Comments:

Curator's name	Location	Crop(s)

Signature	Date

Plant Exchange Office
USDA/ARS, Beltsville, Maryland

GUIDELINES FOR CONDUCT OF FOREIGN PLANT EXPLORATIONS

Plant explorations to foreign countries are an extremely effective means of acquiring genetic resources of interest to national and international programs. A plant explorer on a trip sponsored by the National Plant Germplasm System (NPGS) is essentially a foreign emissary of the United States Government and is expected to be diplomatic, respectful, and courteous while a guest in a host country. It is of utmost importance that all participants in NPGS sponsored explorations are aware that their actions, while in foreign countries, can have a significant effect not only on the success of their particular trip, but, ultimately, on opportunities for future NPGS exploration trips. With this in mind, the Plant Exchange Office (PEO) has listed some ethical considerations for foreign travelers. Since all situations can not be predicted, this list is intended only to guide a prospective plant collector in the type of thinking and sensitivities necessary to ensure that cultural, racial, religious, scientific and political biases do not become impediments to successful plant explorations.

The plant exploration process can be broken down into several elements; 1) Planning and preparing an exploration proposal, 2) Pretrip preparation following funding, 3) Pretravel preparation in host country prior to collecting, 4) Fieldwork and collecting, 5). Post-fieldwork sorting and cleanup at host institution, 6) Follow-up upon return to home country. Each of these elements has certain requirements which must be met for a successful exploration. Each also involves choices as to whether or not those requirements are met in an ethical manner. Suggested ethics for conduct in each phase of the exploration process are presented below.

PLANNING AND PREPARING AN EXPLORATION PROPOSAL

Contact potential host country collaborators as early as possible in planning an expedition - before submission for funding in any case. It is not only courteous to notify hosts of research plans, but also a NPGS requirement to obtain permits for collecting activities. Some countries require one year advance notification.

Determine how your proposed expedition may benefit national programs in the host country, either through acquisition of germplasm or transfer of scientific knowledge. Host country scientists must be included in the planning process. Host country graduate students are often eager to interact with foreign scientists and can benefit greatly by participating in plant explorations.

Determine in advance where collections will ultimately be deposited and who will have access to them. All germplasm collectors must be prepared to share equally with the host country. Collectors must comply with all host country rules and regulations on access to genetic resources. Germplasm collected with NPGS support will be deposited with the NPGS where it may be curated on behalf of the U.S. Government and become available to bona fide users, domestic or foreign. Germplasm collected on NPGS-supported explorations is not patented by the U.S. Government and is available for distribution. While the NPGS will notify recipients of any restrictions on particular accessions, it does not have control over how the end user might utilize germplasm. Host countries may request certain restrictions or requirements concerning intellectual property rights. In this case, the explorer should defer to the USDA/ARS National Program Leader (Plant Germplasm) for guidance. Again, this and all other potential restrictions must be clarified in advance of any collecting.

If possible, determine who will provide transportation and how costs will be shared. If host country institutions will provide a vehicle, it is customary for visitors to cover all operating expenses, maintenance, and most repairs (except perhaps full cost of major repairs). In addition, it is not unreasonable for hosts to require reimbursement in the form of a rental agreement. This should be agreed to in advance to eliminate later misunderstanding. Besides expenses, host institutions may require that U.S. collaborators provide per diem for host collaborators.

When a proposal is submitted to the NPGS, written proof of host country interest and collaboration is required, both from collaborating scientists and their institutional support.

Collaborators should be notified when the proposal is submitted to the NPGS and be given a copy of the final proposal, if it is jointly submitted.

PRE-TRIP PREPARATIONS

Notify collaborators upon NPGS approval of proposal.

Make sure that all permits in host country are applied for well in advance.

Prepare a list of equipment and supplies which must be purchased and carried to host country. Unless prior arrangements have been made, do not assume that host institutions will be able to supply expeditions with plant presses, corrugates, paper bags, envelopes, field labels etc. Find out in advance if you can bring hard-to-get supplies or materials needed by host country collaborators.

Ask host country scientists if they are interested in receiving any germplasm that can be provided from the NPGS collections. If so, arrange to carry the germplasm with you. Obtain any necessary import permits and phytosanitary certificates before departure. Consider taking copies of PCGRIN for crops of interest to host country scientists.

Visiting scientists should offer to present guest lectures at host institutions. They should travel with one or more lectures on activities of their home institution or their current research. Slides or other visual aids are useful. Scientific literature and a scientists' reprints are often the most valued gifts which can be left behind in host countries. Difficult to obtain publications and books are usually welcome contributions to host institutions. Ask in advance what literature is most needed.

TRAVEL PREPARATION IN HOST COUNTRY

Meet all collaborators, hosts, and government officials. Visits to government offices are important and appropriate.

Present seminars, share research activities and talk to graduate students.

Discuss with host colleagues the final responsibilities for trip expenses and how germplasm will be collected and divided.

FIELDWORK AND COLLECTING

Approach all plant collecting with a conservation ethic in mind. Do not collect so as to endanger any natural plant population. Leave sufficient material behind so a plant population can naturally regenerate. For cultivated material, acknowledge the contribution of germplasm shared by farmers.

Respect the local farmers, who are the trustees of local genetic material, for their knowledge and continued preservation of the crop landraces they grow. Work with them; in most cases they have extremely useful information to share about how and why certain plants are grown.

Do not expect your hosts to work on national holidays. Respect their political or religious holidays as well as any important religious observances.

Follow your hosts' lead in observing local customs and behavior. While your preferred field attire may seem entirely appropriate in your home country, it may not be appropriate in foreign settings.

Be respectful when photographing people and sensitive sites. Always ask permission to take photographs of people. It is appropriate for people to ask for

duplicates of photographs you take of them. An instant camera which produces photos immediately can be extremely useful. Do not take photos which would be embarrassing to your hosts.

Avoid "pushing" your hosts to travel to areas where they feel uncomfortable. There may be good reasons for their reluctance to venture into areas of local unrest, even though desired germplasm is known to occur there.

Consider the need for voucher herbarium specimens for study by specialists in the NPGS and host countries. Wild species in particular should be documented by herbarium specimens and duplicates offered to the host country. Photos documenting plant habit and habitat provide a valuable reference.

Take detailed notes and collecting information. Your hosts may want to take their own notes, but your data and notes should still be shared with them.

Approach foreign travel as a learning experience, keeping an open mind. There is usually a reason for everything. Do not criticize what may seem unusual or unnecessary by your standards.

A successful expedition requires leadership of both foreign and host scientists working together. Sharing of expertise and knowledge while undertaking fieldwork is essential.

POST-FIELDWORK CLEANUP

Equally divide all collected germplasm and herbarium specimens. Unless otherwise prearranged, if only three seeds are collected, two go to the host institution and one to the NPGS; an alternate arrangement, which may be better under some circumstances, is for the host institution to grow out all of the seed and later ship a modest sample to the NPGS.

It is not unreasonable for a host to require a few days to help you procure the needed phytosanitary certificates or other export permits prior to departure.

Leave a photocopy of your field notes with the host institution. Specify when you expect to send typed notes or labels. Copies on diskette are appreciated by some institutions.

Draft at least a short joint trip report including all collaborators prior to departing the host country.

Discuss with your hosts how they can take part in publishing results from the field collecting. It is ethically correct for them to be involved in publications which result from fieldwork in which they participated.

Be sensitive to host country constraints to germplasm exchange! Host institutions may not be able to release germplasm prior to your departure. If so, be aware that this might be a delicate matter. Respect their prior agreements and requirements. It is better to leave a host country on good terms and receive the germplasm you collected at a later date than to create an unpleasant incident. Your hosts may be following government directives on policy over which they have no control. Do not place your hosts in an embarrassing situation.

FOLLOW-UP UPON RETURN

Promptly send a complete trip report and field collection data in final form to your collaborators and the PEO.

Arrange for shipment of any germplasm requested by your collaborators. Maintain contacts through timely correspondence.

Include hosts in publication plans. Acknowledge all exploration participants in presentations and papers.

Send letters to collaborators, hosts and government officials acknowledging their assistance. Duplicates of select photographs taken on the trip are also appreciated.

Provide the host country with a list of assigned Plant Introduction (PI) numbers when collections have been incorporated into the NPGS.

Do not discuss problems encountered on any trip more widely than is necessary. You and others may want to return some day.

Plant Exchange Office
National Germplasm Resources Laboratory
Rm. 402, Bldg. 003, BARC-West
Beltsville, MD 20705-2350

APPLICATION PROCEDURES AND REQUIREMENTS FOR SCIENTIFIC RESEARCH AND COLLECTING PERMITS

United States Department of the Interior
National Park Service

POLICY AND GENERAL REQUIREMENTS

The National Park Service (NPS) welcomes your interest in considering national parks for your research site. The NPS is responsible for protecting in perpetuity and regulating use of our National Park areas (parks, monuments, battlefields, seashores, recreation areas, etc.). Preserving park resources unimpaired and providing appropriate visitor uses of parks require a full understanding of park natural resource components, their interrelationships and processes, and visitor interests that can be obtained only by the long term accumulation and analysis of information produced by science. The NPS has a research mandate to provide management with that understanding, using the highest quality science and information. Superintendents increasingly recognize that timely and reliable scientific information is essential for sound decisions and interpretive programming. NPS welcomes proposals for scientific studies designed to increase understanding of the human and ecological processes and resources in parks and proposals that seek to use the unique values of parks to develop scientific understanding for public benefit.

When is a permit required?

A Scientific Research and Collecting Permit is required for most scientific activities pertaining to natural resources or social science studies in National Park System areas that involve fieldwork, specimen collection, and/or have the potential to disturb resources or visitors. When permits are required for scientific activities pertaining solely to cultural resources, including archeology, ethnography, history, cultural museum objects, cultural landscapes, and historic and prehistoric structures, other permit procedures apply. The park's Research and Collecting Permit Office or Headquarters can provide copies of NPS research-related permit applications and information regarding other permits. Federally funded collection of information from the public, such as when formal surveys are used, may require approval from the Office of Management and Budget.

NPS superintendents may authorize their staff to carry out official duties without requiring an NPS research and collecting permit. NPS staff must comply appropriately with professional standards and with all conditions normally associated with scientific research and collecting permits issued by the park. All other natural and social science research and data collection in a park requires a Scientific Research and Collecting Permit and will be allowed only pursuant to the terms and conditions of the permit.

Additional required permits, approvals, and agreements

In some cases, other federal or state agency permits or approvals may be required before NPS

staff can process an application for a Scientific Research and Collecting Permit. Examples include U.S. Fish and Wildlife Service threatened and endangered species permits and migratory bird permits and approvals by an Institutional Animal Care and Use Committee. It is the responsibility of the principal investigator to provide NPS with copies of such permits when they submit an application. Applicants are encouraged to contact park staff to determine if additional permits may be required in conjunction with a proposed study.

Separate agreements between the investigator and NPS are required when proposed studies or collected specimens are intended to support commercial research activities.

Who may apply?

Any individual may apply if he/she has qualifications and experience to conduct scientific studies or represents a reputable scientific or educational institution or a federal, tribal, or state agency.

When to apply?

We recommend that you apply at least 90 days in advance of your first planned field activities. Projects requiring access to restricted locations or proposing activities with sensitive resources, such as endangered species or cultural sites, usually require extensive review and can require 90 days or longer for a permitting decision. Simple applications can often be approved more quickly.

How and where to apply?

An individual may obtain application materials via the Internet (find "Research Permit and Reporting System" at http://science.nature.nps.gov/research or through www.nps.gov) or by contacting the park in which the work will be conducted. Addresses for NPS areas are listed on the NPS Internet web site (www.nps.gov) or may be obtained by contacting the NPS Public Affairs Office via telephone number 202-208-4747. All application materials must be submitted to the NPS area in which you plan to work. You may submit this information via Internet or traditional postal service.

Study proposals

Applications for Research and Collecting Permits must include a research proposal. Proposals must include, as appropriate, all elements outlined in the separate document *Guidelines to Researchers for Study Proposals.*

Review of proposals

Each proposal will be reviewed for compliance with National Environmental Policy Act (NEPA) requirements and other laws, regulations, and policies. The superintendent may also require internal and/or external scientific review, depending on the complexity and sensitivity of the work being proposed and other factors. You can expedite review of your proposal by providing

photocopies of existing peer reviews, or by providing names, mailing addresses, and email addresses of persons that you wish to recommend to review your proposal. Specific details about the review process may be included with the application materials provided by that park.

Facilitating a favorable decision

The superintendent makes a decision to approve a research and collecting permit based on an evaluation of favorable and unfavorable factors (see examples, below), and on an assessment of perceived risks and benefits. While park managers will work with applicants to arrive at a mutually acceptable research design, there may be activities where no acceptable mitigating measures are possible and the application may be denied.

The time and effort required to review the permit application and accompanying study proposal will be proportional to the type and magnitude of the proposed research. For example, a single visit for a non-manipulative research project will often require a relatively simple proposal and the permitting decision should be relatively fast. A highly manipulative or intrusive investigation, however, with the potential to affect non-renewable, rare, or delicate resources, needing detailed planning or logistics, would receive more extensive review. Some of the predisposing factors that influence permitting decisions are outlined below.

Favorable factors

The proposed research:

- contributes information useful to an increased understanding of park resources, and thereby contributes to effective management and/or interpretation of park resources; provides for scheduled sharing of information with park staff, including any manuscripts, publications, maps, databases, etc., which the researcher is willing to share;
- addresses problems or questions of importance to science or society and shows promise of making an important contribution to humankind's knowledge of the subject matter;
- involves a principal investigator and support team with a record of accomplishments in the proposed field of investigation and with a demonstrated ability to work cooperatively and safely, and to accomplish the desired tasks within a reasonable time frame;
- provides for the investigator(s) to prepare occasional summaries of findings for public use, such as seminars and brochures;
- minimizes disruption to the park's natural and cultural resources, to park operations, and to visitors;
- discusses plans for the cataloging and care of collected specimens;
- clearly anticipates logistical needs and provides detail about provisions for meeting those needs; and
- is supported academically and financially, making it highly likely that all fieldwork, analyses, and reporting will be completed within a reasonable time frame.

Unfavorable factors

The proposed research:

- involves activities that adversely affect the experiences of park visitors;

- shows potential for adverse impact on the park's natural, cultural, or scenic resources, and particularly to non-renewable resources such as archeological and fossil sites or special-status species (the entire range of adverse impacts that will be considered also includes construction and support activities, trash disposal, trail conditions, and mechanized equipment use in sensitive areas);
- shows potential for creating high risk of hazard to the researchers, other park visitors, or environments adjacent to the park;
- involves extensive collecting of natural materials or unnecessary replication of existing voucher collections; requires substantial logistical, administrative, curatorial, or project monitoring support by park staff; or provides insufficient lead time to allow necessary review and consultation;
- is to be conducted by a principal investigator lacking scientific institutional affiliation and/or recognized experience conducting scientific research; and
- lacks adequate scientific detail and justification to support the study objectives and methods.

Park response

The principal investigator should receive notice of the approval or rejection of the application by written correspondence via mail, electronic mail, or facsimile. If modifications or changes in a study proposal initially deemed unacceptable would make the proposal acceptable, the park may suggest them at this time. If the application is rejected, the applicant may consult with the appropriate NPS Regional Science Advisor to clarify issues and assess the potential for reconsideration by the park.

Permittee response

If your permit request is approved by the park, you will receive a copy of the permit that you must sign and return to the park via mail or fax. Once the park receives a copy of the permit that you have signed, appropriate NPS officials will validate it and return an approved copy to you. You must carry a copy of the approved permit at all times while performing your research or collecting in the park.

Permit stipulations

General Conditions (requirements and restrictions) will be attached to all Research and Collecting Permits issued. These conditions must be adhered to by permit recipients. Additional Park-specific Conditions may also be included that address unique park resources or activities. An NPS permit is valid only for the activities authorized in the permit. The principal investigator must notify the NPS in writing of any proposed changes. Requests for significant changes may necessitate re-evaluation of the permit conditions or development of a revised proposal.

Access permit requirements

Some NPS areas require access permits for off-road travel, camping, and other activities. Access to many areas is limited and popular destinations can be booked several months in advance.

Please contact the park's Research and Collecting Permit Office to obtain information on any needed access permits.

Research products and deliverables

Researchers working in NPS areas are required to complete an NPS Investigator's Annual Report form for each year of the permit, including the final year. The NPS maintains a system enabling researchers to use the Internet to complete and submit the Investigator's Annual Report. NPS staff will contact permit holders near the beginning of each calendar year to request the prior year's report and explain how to access and use the system. Investigator's Annual Reports are used to consistently document accomplishments of research conducted in parks. Principal investigators are responsible for the content of their reports. NPS staff will not modify reports received unless requested to do so by the principal investigator responsible for the report.

Park research coordinators may request copies of field notes, data, reports, publications and/or other materials resulting from studies conducted in NPS areas. Additional deliverables may be required of studies involving NPS funding or participation.

Privacy Act and Paperwork Reduction Act

NPS regulations (36 CFR 2.1) prohibit possessing, destroying, injuring, defacing, removing, digging, or disturbing from their natural state in any form animals, plants, paleontological, or mineral resources. NPS regulations (36 CFR 2.5) require researchers wishing to conduct research involving acts prohibited by other regulations, such as CFR 2.1, to obtain a specimen collection permit. The National Parks Omnibus Management Act of 1998 (Public Law 105-391) encourages use of parks for science, encourages publication of the results of research conducted in parks, and requires that research conducted in parks be consistent with park laws and management policies. This law also requires that research be conducted in a manner that poses no threat to park resources or public enjoyment. National Park Service Management Policies state that research activities that might disturb resources or visitors, that require the waiver of any regulation, or that involve the collection of specimens may be allowed only pursuant to terms and conditions of an appropriate permit.

The information you submit in your Application for a Scientific Research and Collecting Permit will be used by park managers to determine whether or not to issue you a Scientific Research and Collecting Permit. The information you submit in your Investigator's Annual Report will be used by park managers to inform resource management decision-makers, park visitors, the public, and other researchers about the objectives and progress results of your research.

Parks and park records are public assets. The information you submit in your Application and in your Investigator's Annual Report is not confidential and will be in the public record and available to the public. If you want to receive and maintain a Scientific Research and Collecting Permit, you must respond to both the Application and Investigator's Annual Report collections of information. If you do not respond to the request for information in the Application, you will not be considered for a Scientific Research and Collecting Permit. If you have received a Scientific Research and Collecting Permit and do not respond to the request for information in

the Investigator's Annual Report, your permit may be revoked and you may be denied future permits.

The Application for a Scientific Research and Collecting Permit and the Investigator's Annual Report are two parts of one complete process dealing with conducting scientific research and collecting in a unit of the National Park System. The total public reporting burden involved in electronically completing the collection of information process for a single scientific research and collecting activity in a unit of the National Park System includes the burden of reading the informational documents associated with these two information collection forms plus completing and submitting one Application form (approximately 45 minutes), plus the burden of signing and mailing an issued permit back to the park (approximately 15 minutes), plus the burden of completing one associated Investigator's Annual Report form (approximately 15 minutes). Some applicants will experience an additional burden of photocopying and mailing attachments (approximately 15 minutes). Other applicants will experience an additional burden of coordinating with a specimen repository (approximately 30 minutes). The total public reporting burden experienced by a successful permittee for electronically completing this process for a single scientific research and collecting activity in a unit of the National Park System thus is estimated to range between 1.25 and 2.0 hours per year. The total public reporting burden experienced by an unsuccessful applicant for electronically completing this process is estimated to be about 45 minutes per year because the unsuccessful applicant will not be required to complete the Investigator's Annual Report, mail a signed permit, or respond to other portions of the process. The few applicants who complete these forms manually are expected to experience a somewhat larger annual reporting burden. Direct any comments you may have regarding this burden estimate or any other aspect of this information collection process or of its two forms to the Office of Information and Regulatory Affairs of OMB, Attention Desk Officer for the Interior Department, Office of Management and Budget, Washington, DC 20503; and to the Information Collection Clearance Officer, WASO Administrative Program Center, National Park Service, 1849 C Street, N.W., Washington, DC 20240.

GUIDELINES TO RESEARCHERS FOR STUDY PROPOSALS

United States Department of the Interior
National Park Service

Your proposal should include each of the required information items listed below, in enough detail that an educated non-specialist can understand exactly what you plan to do. If you have already prepared a relevant proposal for a funding application, work plan, formal agreement, or similar document, then your original proposal likely will satisfy National Park Service (NPS) proposal requirements. The primary area where new information may be necessary concerns the ability of the park to assess what, if any, impacts your research may have on park resources. You should compare your original proposal to these guidelines to be certain that you have provided all the required information. If additional information is required, you can provide it in a cover letter or supplement to your proposal, as appropriate. If a required topic does not apply to your proposed study, simply list the topic and write "not applicable."

The length of your proposal depends primarily on the complexity of the work planned. In some cases, a proposal may consist of a couple of pages for a study expected to have no significant impact on park resources or visitor experiences. However, proposals for lengthy or complex research problems, for extensive collecting, and for work with special status species or sensitive cultural resources are typically longer, more detailed, and well-organized. Incomplete, disorganized, or illegible proposals may be returned for revision.

I. INTRODUCTION

A. **Title**

B. **Date of proposal**

C. **Investigators** - Provide the name, title, address, telephone number, FAX number, email address, and institutional affiliation of the principal investigator and the name and affiliation of all additional investigators listed in the proposal.

D. **Table of contents** - Recommended for long or complicated proposals.

E. **Abstract** - Provide a brief summary description of the proposed project. Include up to five keywords that can be used by the NPS to quickly identify the proposal subject (for example, microbiology, geology, ecology).

II. OVERVIEW

OVERVIEW - Summarize the proposed project by describing in general the problem or issue being investigated as well as any previous pertinent research.

A. **Statement of issue** - Describe the issue to be investigated and its importance and relevance to science and to the park. Provide relevant background information that clarifies the need for the project and why it is valuable for the research and/or collecting to be conducted in the park.

B. **Literature summary** - Summarize the relevant literature regarding the issue, problem, or questions that will be investigated.

C. **Scope of study** - Describe the overall geographic and scientific scope of the project.

D. **Intended use of results** - Describe how the products will be used, including any anticipated commercial use.

III. **OBJECTIVES/HYPOTHESES TO BE TESTED** - Describe the specific objectives of the proposed project. Where appropriate, the objectives should be stated as specific hypotheses to be tested.

IV. **METHODS** - Describe how the proposed methods and analytical techniques will achieve the study objectives or test the stated hypothesis/question. Provide pertinent literature citations.

A. **Description of study area** – Clearly describe the study area in terms of park name(s), geographic location(s), and place names. Provide maps, park names, or geographic coordinates as appropriate. Indicate whether your work will take place in an area designated or managed as "wilderness" by the NPS.

B. **Procedures** - Describe the proposed study design that addresses the stated objectives and hypotheses. Explain the methods and protocols to be employed in the field and laboratory.

C. **Collections** - Describe the type, size, and quantity of specimens or materials to be collected, sampled, or captured, and your plans to remove them from the collecting site. If you are aware specimens of the proposed types already exist in a repository, explain why additional collecting is necessary. Provide scientific nomenclature where possible. Provide information on all other applicable federal or state permits where required.

D. **Analysis** - Explain how the data from the study will be analyzed to meet the stated objectives or test the hypotheses. Include any statistical techniques or mathematical models necessary to the understanding of the analysis.

E. **Schedule** - Provide a schedule that includes start of project, approximate dates or seasons of fieldwork, analysis, reporting, and completion dates.

F. **Budget** - Briefly outline the expenses associated with this project and identify your expected funding source(s). Include the anticipated costs pertaining to the cataloging of collected and permanently retained specimens or materials.

V. PRODUCTS

A. **Publications and reports** - Describe the expected publications or reports that will be generated as part of this study.

B. **Collections** – Describe the proposed disposition of collected specimens or materials. If you propose that the NPS lend the specimens or samples to a non-NPS institution for long-term storage, identify that institution and give a brief justification for this proposal.

C. **Data and other materials** - Describe any other products to be generated as part of the project, such as, photographs, maps, models, handouts, exhibits, software presentations, raw data, GIS coverages, or videos, and the proposed disposition of these materials. If data are to be collected from the public as part of this study, provide a copy of the data collection instrument (survey, questionnaire, interview protocol, etc.).

VI. LITERATURE CITED

- Include full bibliographic citations for all reports and publications referenced in the proposal.

VII. QUALIFICATIONS

- Provide a background summary or curriculum vitae for the principal investigator and other investigators listed in the proposal. Identify their training and qualifications relevant to the proposed project and their ability to conduct field activities in the environment of the proposed study area. Describe previous research and collecting in NPS areas, including study and permit numbers if available.

VIII. SUPPORTING DOCUMENTATION AND SPECIAL CONCERNS

- Provide information on the following topics where applicable. Attach copies of any supporting documentation that will facilitate processing of your application, such as other required federal and state permits, copies of peer reviews, letters of support and funding commitments, and certifications. Collection of information from the public when federal funds are used may require approval from the Office of Management and Budget (OMB). Upon your request, the NPS Social Science Program will advise you on steps needed to obtain this OMB approval.

A. **Safety** - Describe any known potentially hazardous activities, such as electrofishing, rock climbing, scuba diving, whitewater boating, aircraft use,

wilderness travel, wildlife capture, handling or immobilization, use of explosives, etc.

B. **Access to study sites** - Describe the proposed method and frequency of travel to and within the study site(s). Explain any need to enter restricted areas. Describe duration, location, and number of participants for planned backcountry camping.

C. **Use of mechanized and other equipment** - Describe any field equipment, markers, or supply caches by type, number, and location. You should explain how long they are to be left in the field. Explain the need to use these materials in restricted areas and the alternatives that were considered.

D. **Chemical use** - Identify any chemicals and hazardous material that you propose using within the park. Indicate the purpose, method of application, and amount to be used. Describe plans for storage, transfer, and disposal of these materials and describe steps to remediate accidental releases into the environment. Attach copies of Material Safety Data Sheets.

E. **Ground disturbance** - Describe the type, location, area, depth, number, and distribution of expected ground-disturbing activities, such as soil pits, cores, stakes, or latrines. Describe plans for site restoration of significantly affected areas.

Proposals that entail ground disturbance may require an archeological survey and special clearance prior to approval of the study. You can help reduce the extra time that may be required to process such a proposal by including identification of each ground disturbance area on a USGS 7.5-minute topographic map.

F. **Animal welfare** - For vertebrate species that require review by your Institutional Animal Care and Use Committee (IACUC) according to the Animal Welfare Act, please include a photocopy of the study protocol, and IACUC review form and approval.

For vertebrate species not requiring IACUC review, describe your protocol for any capture, holding, marking, tagging, tissue sampling, or other handling of these animals (including the training and qualifications of personnel relevant to animal handling and care). Please discuss alternative techniques considered and outline any procedures to alleviate pain or distress. Include contingency plans to be implemented in the event of accidental injury to or death of the animal.

G. **NPS assistance** - Describe any NPS field assistance you would like to receive to complete the proposed study, such as use of equipment or facilities or assistance from staff.

H. **Wilderness "minimum requirement" protocols** - If some or all of your activities will be conducted within a location administered by the NPS as a

designated, proposed, or potential wilderness area, your proposal should describe how the project adheres to wilderness "minimum requirement" and "minimum tool" concepts. Refer to the park's wilderness management plan for further information.

GENERAL CONDITIONS

For

SCIENTIFIC RESEARCH AND COLLECTING PERMIT

United States Department of the Interior
National Park Service

1. **Authority** - The permittee is granted privileges covered under this permit subject to the supervision of the superintendent or a designee, and shall comply with all applicable laws and regulations of the National Park System area and other federal and state laws. A National Park Service (NPS) representative may accompany the permittee in the field to ensure compliance with regulations.

2. **Responsibility** - The permittee is responsible for ensuring that all persons working on the project adhere to permit conditions and applicable NPS regulations.

3. **False information** - The permittee is prohibited from giving false information that is used to issue this permit. To do so will be considered a breach of conditions and be grounds for revocation of this permit and other applicable penalties.

4. **Assignment** - This permit may not be transferred or assigned. Additional investigators and field assistants are to be coordinated by the person(s) named in the permit and should carry a copy of the permit while they are working in the park. The principal investigator shall notify the park's Research and Collecting Permit Office when there are desired changes in the approved study protocols or methods, changes in the affiliation or status of the principal investigator, or modification of the name of any project member.

5. **Revocation** - This permit may be terminated for breach of any condition. The permittee may consult with the appropriate NPS Regional Science Advisor to clarify issues resulting in a revoked permit and the potential for reinstatement by the park superintendent or a designee.

6. **Collection of specimens (including materials)** - No specimens (including materials) may be collected unless authorized on the Scientific Research and Collecting permit.

The general conditions for specimen collections are:

- Collection of archeological materials without a valid Federal Archeology Permit is prohibited.
- Collection of federally listed threatened or endangered species without a valid U.S. Fish and Wildlife Service endangered species permit is prohibited.
- Collection methods shall not attract undue attention or cause unapproved damage, depletion, or disturbance to the environment and other park resources, such as historic sites.
- New specimens must be reported to the NPS annually or more frequently if required by the park issuing the permit. Minimum information for annual reporting includes specimen classification, number of specimens collected, location collected, specimen status (e.g., herbarium sheet, preserved in alcohol/formalin, tanned and mounted, dried and boxed, etc.), and current location.
- Collected specimens that are not consumed in analysis or discarded after scientific analysis remain federal property. The NPS reserves the right to designate the repositories of all specimens removed from the park and to approve or restrict reassignment of specimens from one repository to another. Because specimens are Federal property, they shall not be destroyed or discarded without prior NPS authorization.
- Each specimen (or groups of specimens labeled as a group) that is retained permanently must bear NPS labels and must be accessioned and cataloged in the NPS National Catalog. Unless exempted by additional park-specific stipulations, the permittee will complete the labels and catalog records and will

provide accession information. It is the permittee's responsibility to contact the park for cataloging instructions and specimen labels as well as instructions on repository designation for the specimens.

- Collected specimens may be used for scientific or educational purposes only, and shall be dedicated to public benefit and be accessible to the public in accordance with NPS policies and procedures.

- Any specimens collected under this permit, any components of any specimens (including but not limited to natural organisms, enzymes or other bioactive molecules, genetic materials, or seeds), and research results derived from collected specimens are to be used for scientific or educational purposes only, and may not be used for commercial or other revenue-generating purposes unless the permittee has entered into a Cooperative Research And Development Agreement (CRADA) or other approved benefit-sharing agreement with the NPS. The sale of collected research specimens or other unauthorized transfers to third parties is prohibited. Furthermore, if the permittee sells or otherwise transfers collected specimens, any components thereof, or any products or research results developed from such specimens or their components without a CRADA or other approved benefit-sharing agreement with NPS, permittee will pay the NPS a royalty rate of twenty percent (20%) of gross revenue from such sales or other revenues. In addition to such royalty, the NPS may seek other damages to which the NPS may be entitled including but not limited to injunctive relief against the permittee.

7. **Reports** - The permittee is required to submit an Investigator's Annual Report and copies of final reports, publications, and other materials resulting from the study. Instructions for how and when to submit an annual report will be provided by NPS staff. Park research coordinators will analyze study proposals to determine whether copies of field notes, databases, maps, photos, and/or other materials may also be requested. The permittee is responsible for the content of reports and data provided to the National Park Service.

8. **Confidentiality** - The permittee agrees to keep the specific location of sensitive park resources confidential. Sensitive resources include threatened species, endangered species, and rare species, archeological sites, caves, fossil sites, minerals, commercially valuable resources, and sacred ceremonial sites.

9. **Methods of travel** - Travel within the park is restricted to only those methods that are available to the general public unless otherwise specified in additional stipulations associated with this permit.

10. **Other permits** - The permittee must obtain all other required permit(s) to conduct the specified project.

11. **Insurance** - If liability insurance is required by the NPS for this project, then documentation must be provided that it has been obtained and is current in all respects before this permit is considered valid.

12. **Mechanized equipment** - No use of mechanized equipment in designated, proposed, or potential wilderness areas is allowed unless authorized by the superintendent or a designee in additional specific conditions associated with this permit.

13. **NPS participation** - The permittee should not anticipate assistance from the NPS unless specific arrangements are made and documented in either an additional stipulation attached to this permit or in other separate written agreements.

14. **Permanent markers and field equipment** - The permittee is required to remove all markers or equipment from the field after the completion of the study or prior to the expiration date of this permit. The superintendent or a designee may modify this requirement through additional park specific conditions that

may be attached to this permit. Additional conditions regarding the positioning and identification of markers and field equipment may be issued by staff at individual parks.

15. **Access to park and restricted areas** - Approval for any activity is contingent on the park being open and staffed for required operations. No entry into restricted areas is allowed unless authorized in additional park specific stipulations attached to this permit.

16. **Notification** - The permittee is required to contact the park's Research and Collecting Permit Office (or other offices if indicated in the stipulations associated with this permit) prior to initiating any fieldwork authorized by this permit. Ideally this contact should occur at least one week prior to the initial visit to the park.

17. **Expiration date** - Permits expire on the date listed. Nothing in this permit shall be construed as granting any exclusive research privileges or automatic right to continue, extend, or renew this or any other line of research under new permit(s).

18. **Other stipulations** - This permit includes by reference all stipulations listed in the application materials or in additional attachments to this permit provided by the superintendent or a designee. Breach of any of the terms of this permit will be grounds for revocation of this permit and denial of future permits.

PRINCIPLES FOR ACCESSING GENETIC RESOURCES, THE TREATMENT OF INTELLECTUAL PROPERTY AND THE SHARING OF BENEFITS ASSOCIATED WITH ICBG-SPONSORED RESEARCH

In developing both research plans and intellectual property agreements, it is important that all involved understand the differences between patent coverage and benefit-sharing agreements. While legal protection of the right to commercialize an invention is generally accomplished through the patent system, agreements among collaborators are generally required to designate the terms of partnerships including, among other things, the licensing of an invention and the sharing of any financial or other benefits that accrue from it.

The conduct of ICBG-sponsored research and the agreements among the collaborators must address the following principles to be eligible for funding.

1. Disclosure to and informed consent of host country stakeholders

a) Plans to collect samples for drug discovery should be vetted with the national government authorities of the host country and with any other national or local organizations they, you or your partners deem appropriate at the earliest stage of planning and once again, formally, before any collections take place.

b) Where national governments do not have clear regulations to guide informed consent procedures, activities should follow a two phase approach to distinguish basic and commercial research. Basic research intended primarily for publication, including collecting and analyzing biodiversity, as well as bioassay and chemistry work, may be considered "basic" research. If, at any time, researchers intend to file a patent application based on this work or to send a sample for testing to an industrial partner, the research immediately enters the commercial realm and must follow all the requisite permit and contract standards.

c) Arrangements for the use of traditional knowledge or the collection of samples from the lands of local peoples should be based upon full disclosure and informed consent of those peoples. Under best practices such arrangements develop as a partnership with early and ongoing full participation of appropriate community representatives in project design.

d) Indigenous concepts of intellectual property should be respected. If, for instance, cooperating indigenous groups, on the basis of religious or other concerns, object to specific uses, widespread dissemination or other treatments of the knowledge they provide, these concerns should be respected in the conduct of ICBG projects.

e) The process of disclosure and informed consent should be as inclusive and formal as is possible and culturally appropriate. The best practice is the development of written agreements with a community following complete and formal mutual agreement on the Group's goals and methods. Presentations by scientists to host country stakeholders

should provide realistic descriptions of the type, amounts and probabilities of benefits, as well as any costs or risks that may accrue to cooperating communities or organizations. Arrangements with individuals who cooperate or provide information should be based upon prior community-level agreements whenever possible or appropriate.

2. Clear designation of the rights and responsibilities of all partners.

a) This is principally done through the design of adequate contractual agreements. Agreements should be among all collaborating organizations, whether or not they are recipients of government funds. These may include commercial drug developers, source country and U.S. research institutions, and indigenous and local peoples whose resources, biological or intellectual, are utilized in the research process.

b) It is strongly recommended that all parties to agreements have separate, competent legal counsel to represent their interests.

c) Useful contractual tools for the designation of rights and responsibilities include material transfer agreements, research and development agreements, license options agreements, know-how licenses, benefit-sharing agreements, and structured trust funds.

d) Unless stipulated otherwise in agreements among source country institutions and their collaborators, biological samples and associated information collected under ICBG-sponsored research is the property of the source country institutions. The Government retains "march-in" rights to require licensing if the inventing organization(s) fail to pursue development of the process or invention, as described in the "Terms and Conditions of Award."

e) The ownership and compensation terms of first generation and subsequent inventions based upon a lead discovered in ICBG work should be clearly stipulated in agreements.

f) Agreements should specify that the basic goals of the collaboration include drug discovery, economic opportunities, and the conservation and sustainable use of biological diversity.

g) Agreements should also indicate how a sustainable source of materials for follow-up analysis of a lead compound will be developed, and should preferentially use the participating country and/or communities as the first source of raw or processed materials.

3. Protection of inventions using patents or other legal mechanisms.

a) Non-profit organizations (including universities) and small business firms retain the rights to any patents resulting from U.S. Government contracts, grants, or Cooperative Agreements. PL 96-517, through regulation, extends to businesses of any size the first option to the ownership of rights to inventions made in the performance of a federally-funded contract, grant, or Cooperative Agreement. All group members, therefore,

including businesses of any size, might be full partners in the research of the Group and in rights to file patents for any inventions resulting therefrom as specified in the Group's research agreement(s). This includes communities organized into or represented by an appropriate legal entity.

b) The specific intellectual property arrangements among the institutions may vary and could include joint patent ownership, exclusive licensing arrangements, etc. Valuable intellectual resources that cannot or will not be patented, such as novel assays or traditional medicinal techniques, may require alternative protection methods, such as trade secrets. Applicants are encouraged to develop an arrangement that best suits the particular circumstances of their Group.

4. Sharing of benefits with the appropriate source country parties.

a) Equitable distribution of benefits should accrue to all those who contribute to a commercialized product, whether they are members of the consortium or not, including research institutions and local or indigenous people who provide useful traditional knowledge.

b) Benefits should flow back to the area in which the source plant, animal or microorganism was found, in such a way that they at least indirectly promote conservation of biological diversity.

c) The selection of beneficiaries must be justified in terms of program goals, as well as local and international laws and customs.

d) Benefits should be structured such that they are appropriate to the needs of the communities and the resources of the other collaborators. For example, trust funds managed by a community or community-project board may be more effective in support of conservation and health or education services than cash payments to a single individual or authority. Note that direct cash compensation may even have injurious effects on non-money economies.

e) Ideally, compensation begins flowing early in the collaboration through initial payments, training, equipment or services, to provide near-term conservation incentives.

5. Information flow that balances proprietary, collaborative and public needs.

a) Agreements and research plans should anticipate the tension between the traditional scientific ethic of public access to information, including publication of results, and the understandable desire of indigenous or commercial partners for confidentiality of information with potential commercial value, pending protection through patenting or other means.

b) Sharing of information among collaborating organizations should be an ongoing and regular process and should be as complete as possible to maximize efficiency of research

and equity in partnerships while recognizing the proprietary concerns of those partners. Reporting back to collaborating communities, where relevant, on significant project developments should be a regular and expected component of the project.

6. Respect for and compliance with relevant national and international laws, conventions and other standards.

a) Relevant international conventions, such as the United Nations Convention on Biological Diversity and national laws regarding study, use and commercialization of chemical, biological and cultural resources, should be observed rigorously in the development of agreements and the conduct of research.

b) An essential goal of this program is to develop models for sustainable and equitable commercial use of biodiversity-rich ecosystems. As such, ICBG research agreements and activities should, wherever possible, go beyond the minimum legal standards regarding international research collaborations, looking to best practices and other standards for guidance.

DEFINITIONS

ADVISORY COMMITTEE: A subset of two or more U.S. Government scientific advisers from the Technical Advisory Group (TAG) to assist the work of the Group by providing advice and assistance and through the Scientific Coordinator (Committee Chair), to the Group. The Advisory Committee assists in such matters as reviewing the Group's progress reports and suggesting mid-course corrections and future directions for the Group. The Advisory Committee assembled for each Group is determined by the TAG. Each committee, including the Scientific Coordinator, attends groups meetings, where possible, meets separately at least once per year, and maintains ongoing communication regarding group progress.

ASSOCIATE PROGRAM: A component of the overall Group with a separate, detailed program plan and budget, that brings to the Group a unique resource, capability or expertise.

ASSOCIATE PROGRAM LEADER: The director of one of the Associate Programs of the ICBG.

BOTANICAL: A preparation of plant-based materials used as a form of healthcare in its whole or extracted form, including various chemical constituents, rather than as a single isolated compound. For the purposes of this RFA, botanicals include "phytomedicines" and may also include preparations of non-plant biological materials used similarly but derived from terrestrial or marine sources including fungal, bacterial or animal origin.

CENTRAL OPERATIONS OFFICE: An administrative unit located at the Group Leader's institution, which is responsible for coordinating and/or providing administrative support for all Group activities including budgets from the Group's associate programs.

COOPERATIVE AGREEMENT: An assistance mechanism in which substantial Government scientific and programmatic involvement with the recipient is anticipated during performance of the planned activity.

CONTRACTUAL AGREEMENT: Any formal written agreement negotiated among participating institutions in an ICBG, or between the ICBG and other organizations, that stipulates the rights and responsibilities of the parties with respect to the research process, the access to genetic resources, treatment of intellectual property and the sharing of benefits.

DEVELOPING COUNTRY: low- and middle-income countries as listed at: http://www.worldbank.org/data/databytopic/class.htm. Note that this economic criterion is a minimal criterion of eligibility. High indices of biodiversity and other scientific features of potential host country sites that enable ICBG research and development activities are an important part of the peer review. If you have questions about the eligibility or competitiveness of a given country or region you are encouraged to contact program staff.

FIC BIODIVERSITY PROGRAM DIRECTOR: A representative of the Fogarty International Center, a member of the TAG, and the Government program administrator for all funded Groups. The Program Director has lead responsibility for day-to-day funding and policy decisions in coordination with the Director of the FIC and the TAG. In conjunction with the Government Scientific Coordinator for each ICBG, the Program Director supports the activities of the Groups, where possible, through policy and program functions.

GROUP LEADER: The Principal Investigator identified in the application who assembles the ICBG, submits the single application in response to this RFA, and who is responsible for the performance of the Group as a whole and of each Associate Program Leader. The Group Leader will coordinate Group activities both scientifically and administratively and, in addition, may lead one of the Associate Programs of the Group. The Group Leader's institution is legally and fiscally accountable for the disbursement of funds awarded. The Group Leader's institution must be a not for-profit institution in the US.

INTERNATIONAL COOPERATIVE BIODIVERSITY GROUP: A consortium of Associate Programs, at least one of which is located in a developing country institution, representing diverse scientific disciplines and organizations which join together under guidance and direction of a single Group Leader (Principal Investigator) and which function as a unit with a common goal: to promote, through multidisciplinary approaches, drug development, biodiversity conservation, and sustainable scientific and economic development. In this RFA, the terms International Cooperative Biodiversity Group, ICBG, and "Group" are used synonymously.

NATURAL PRODUCT: In the context of the ICBG, a term used broadly to encompass any naturally occurring bioactive agent selected for pre-clinical evaluation against a disease or for another medical, agricultural, cosmetic or industrial need. This, of course, excludes materials which are synthesized de novo as well as any semi-synthetic derivatives which do not require the collection of material from nature.

PATENTABLE INVENTION: Any new and useful process, machine, manufacture or composition of matter, or any new and useful improvements thereof, as defined under the U.S. Patent Statute (35 USC 101).

TECHNICAL ADVISORY GROUP (TAG): A committee of advisors with relevant expertise from the Participating Agencies and Institutes, including the Director of the Fogarty International Center (FIC). The TAG reviews applications to make funding recommendations following the initial peer review, and meets several times per year, as necessary, to review developments in the ICBG program as a whole and progress of individual Groups.

U.S. GOVERNMENT SCIENTIFIC COORDINATOR: A representative of the TAG who assists a specific ICBG, attends Group meetings, interacts scientifically with the Group, and facilitates the role of the Government as a participant in the Group. The U.S. Government Scientific Coordinator serves as the chair of his or her respective Advisory Committee.

Background on the Tulalip Cultural Stories Project

The Tulalip Cultural Stories Project was initiated in 1996 by the Tulalip Tribes of Washington as a community-based knowledge management solution to a number of critical cultural needs perceived by the Tribes.

One of their primary concerns is the loss of traditional knowledge that comes in many forms, from language, spiritual beliefs and practices, traditional songs and dances, and oral history to detailed knowledge about the uses of culturally important plants and animals and traditional land management practices. The traditional structures for passing knowledge from elders to the youth had been severely disrupted and the Tribes were experimenting with methods for cultural revitalization. The Tribes had established a cultural center to house permanent archives for records of their traditional knowledge, and to organize education in language and cultural values and practices. They authorized the Cultural Stories Project to extend these activities into biodiversity- and environmentally-related knowledge.

Another major concern was the lack of ability for tribal land managers to access information about the cultural resources and values in the landscape in order to effectively make land management decisions. There was no single list of the plants or animals traditionally used by the tribe, or of the Tribes' sacred sites or other sites of value to the tribe. Knowledge in the tribal community is distributed among its members, with much of the traditional knowledge being held by particular individuals, families, or clans. Tribal resource managers do not necessarily have easy access to this knowledge in order to plan such activities as land acquisitions, harvest regulations, ecological restoration projects, or conservation prioritization. Similar to many non-indigenous government administrations, the resource managers are often concentrated on economically important species, such as clams, Pacific salmon and timber for the Tulalip Tribes. Whatever knowledge was gained on traditional resource management was also lost whenever there was a staff turnover. The Tribes felt that a means of compiling and managing information on the larger variety of cultural values and resources was needed.

Finally, the tribe was becoming committed to cultural landscape restoration, in an effort to recover the ecology and traditional uses of their tribal homelands as far as feasible. To do this, they needed to establish a means of establishing the historical baseline conditions. The Tribes looked to a number of methods from historical accounts, historical scientific studies, and ecological modeling of historical environments. While these provide important information about historical conditions, they also have limitations. Many of the models indicate habitats and species distributions at a scale that is too large for detailed tribal land use planning. The historical accounts are often difficult to interpret and often given from a non-native perspective. The project initiated a project to encourage elders to share their stories about the land, with a focus on getting them to offer details about their knowledge of the past, present, and future desired conditions of the state of their environment. These stories are important guides to the details of

location-specific historical ecology, ecological state and species distributions, and help direct the Tribe to make decisions about conservation priorities.

The Cultural Stories Project is being implemented to weave these issues together. The project has developed methods for interviewing elders and eliciting details about the historical, current and future desired species locations, abundances, qualities and uses, as well as other landscape values. The data are being stored in ICONS, a software system developed to support the indexing of traditional knowledge and managing a range of biodiversity and cultural resources management related information such as customary, tribal statutory regulations, and national and international legislation, bibliographic resources, organization directories, individual contacts, project information, species information, geographic areas information, and related information resources. The software system is being designed to provide multiple levels of access, so that information access may be restricted to members of particular user groups. Some information may be made available openly to the public for public education, some restricted to members of the Tulalip Tribes, some restricted to select natural resource management personnel, and some restricted to the owners of the knowledge, such as individuals, families or clan groups.

The structure of the ICONS system is currently being integrated with geographic information systems (GIS) technology, so that models of the ecological and biogeophysical impacts of changes in watershed values can also be evaluated in terms of their impacts on cultural resources, and the locations and properties of traditional resources can be mapped for internal use by the Tribes. The rights management aspects of the system make it suitable for tribes seeking to establish their own biodiversity registers, and is one model for how a patent registry of indigenous knowledge that protects primary indigenous knowledge could be constructed.

The multiple-layers of access has also led the Tribes to include features in their information management system to manage information sharing with other tribes, with local and national government agencies, and with other parties working on problems held in common. While the detailed information on tribal uses and locations of plants, animals and scared sites is secured for tribal use only, there is a body of compiled information the Tribes is willing to share with others. For example, the project has assembled a large bibliographic database on indigenous knowledge, community-based natural resource development, biodiversity conservation, genetic resources access and benefit-sharing, and biodiversity- and culturally-related intellectual property rights; a directory of indigenous organizations and non-indigenous organizations working on these issues; and a compilation of relevant declarations and laws. These resources are useful to a large number of non-tribal members and do not contain tribal proprietary information. The Tribe is currently working with the Indigenous Biodiversity Information Network (IBIN) to make these accessible over the Internet, and have adopted current electronic standards for indexing these data. The use of standards is viewed as important by the Tribes, because they view the need to move toward creating true, distributed networks of open information sharing on some kinds of information, while maintaining community control and protection over their own knowledge.

In summary, the Cultural Stories Project consists of a set of tribally-developed methodologies for collecting and organizing biodiversity-related traditional knowledge, mostly from interviews with tribal elders, for archival, cultural revitalization and natural resource management issues. The information has been collected and archived under tribal procedures for obtaining prior informed consent. The information collected in the project have been assembled into a software system that manages the information at multiple-levels of access, and the software system provides links to the Western scientific models used by the Tribes for watershed management, as well as GIS technology for resource mapping and spatial analysis. While most of the data are secured for internal tribal use, some is general and non-proprietary, and the system has been designed to allow this information to be shared in open networks using widely used formats. The model can be used to implement other networks where there needs to be a mix of public information sharing and community-based information control.

For more information contact:

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III. SUBMISSIONS FROM RELEVANT ORGANISATIONS

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Reference: **ORG/355 (02-4801)**
(Div. Ref. trips/lt231-CBD)

16 JAN 2003

Dear Mr. Zedan,

In response to your communication of 3 July 2002, in which you invited relevant organizations, including the WTO, to assist the Secretariat of the Convention on Biological Diversity in the preparation of relevant background documentation with regard to the implementation of Decision VI/24 on access and benefit-sharing as related to genetic resources, I am pleased to give you an update of the discussions so far in the WTO Council for TRIPS on related matters.

In 1999, the Council for TRIPS initiated the review of Article 27.3(b) of the TRIPS Agreement, which relates to the patentability of plant and animal inventions. In this context, a number of WTO Members made presentations and raised points regarding access and benefit-sharing as related to genetic resources. A number of issues in this connection were also raised elsewhere in the WTO in the context of "implementation-related issues and concerns" identified by some developing country Members.

On 14 November 2001, Members of the WTO adopted the WTO Doha Ministerial Declaration which, in paragraph 19, instructs the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of the Declaration (regarding implementation-related issues and concerns), to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1.

Pursuant to the Doha mandate, the discussions in the Council for TRIPS on relevant issues have been organized under three agenda items, namely the review of Article 27.3(b), the relationship between the TRIPS Agreement and the Convention on Biological Diversity, and the protection of traditional knowledge and folklore. The work done in the Council for TRIPS from 1999 to March 2002 on each of these sets of issues has been summarized in the Secretariat notes IP/C/W/369, 368, and 370. The discussions in the Council for TRIPS at its meetings of June and September 2002 are recorded in the minutes of the Council for TRIPS IP/C/M/36/Add.1 (paragraph 44 to 59) and IP/C/M/37/Add.1 (paragraph 44 to 62). At those meetings, papers, including certain proposals on access and benefit-sharing, were submitted by the European Communities and their member States (IP/C/W/383), by a group of developing countries namely, Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Peru, Thailand, Venezuela, Zambia and Zimbabwe (IP/C/W/356 and Add.1) and by the United States (IP/C/W/393). Copies of all the above-mentioned documents are enclosed herein.

Please do not hesitate to contact me if you have any further questions or comments.

Yours sincerely,

Adrian Otten
Director
Intellectual Property Division

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JAN 21 2003
ACTION NN
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